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Barthe et al.

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(54) **METHOD AND SYSTEM FOR TREATING ACNE AND SEBACEOUS GLANDS**

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(65) **Prior Publication Data**

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(74) *Attorney, Agent, or Firm*—Snell & Wilmer L.L.P.

Related U.S. Application Data

(57) **ABSTRACT**

(60) Provisional application No. 60/617,203, filed on Oct. 7, 2004.

(51) **Int. Cl.**
A61B 8/00 (2006.01)

(52) **U.S. Cl.** **600/439; 600/437; 601/2**

(58) **Field of Classification Search** **600/439, 600/437, 440; 601/2-4; 607/88; 606/9, 606/10; 128/399; 604/22**

See application file for complete search history.

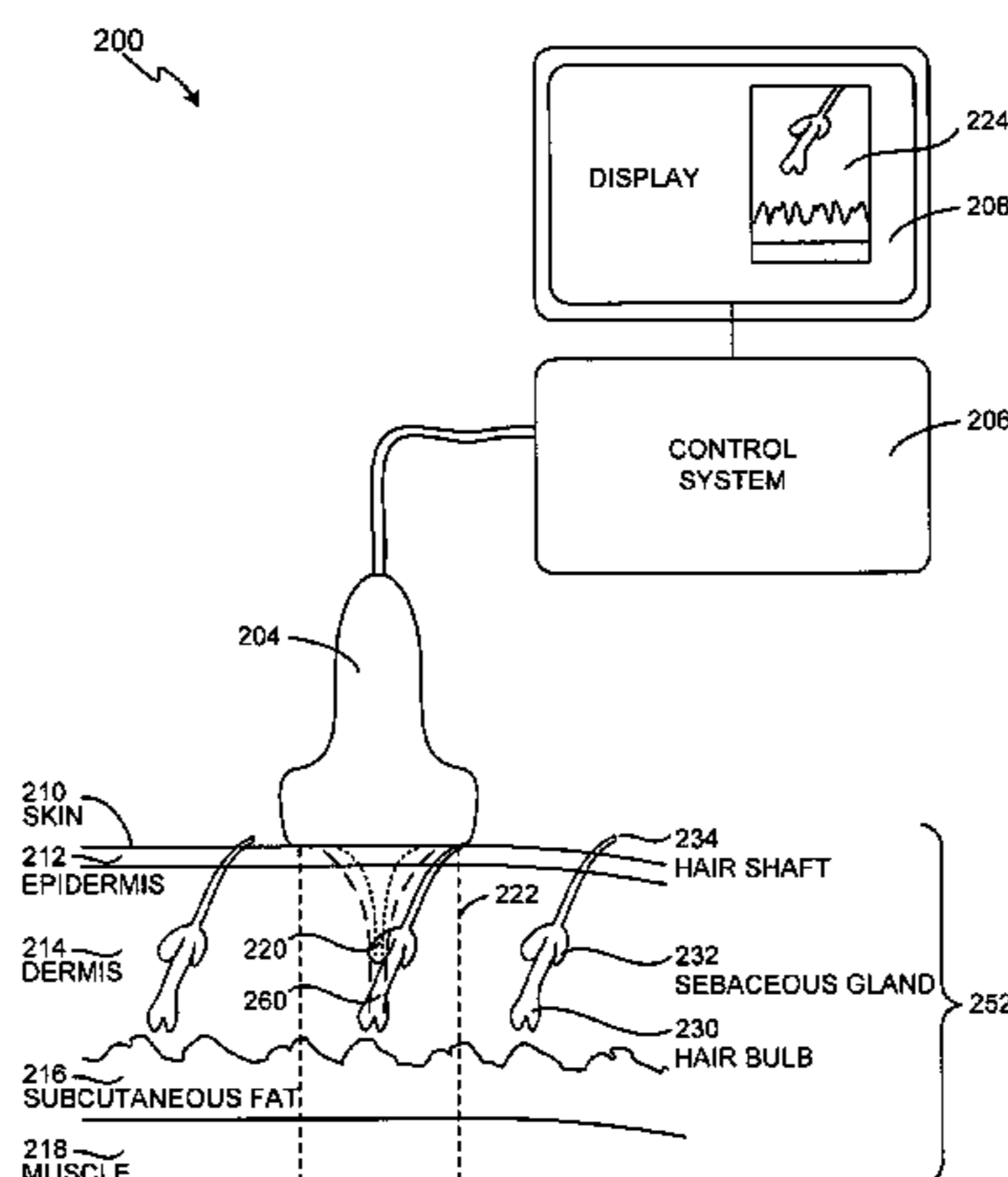
A method and system for ultrasound treatment of acne and sebaceous glands are provided. An exemplary method and system are configured for targeted treatment of sebaceous glands in various manners, such as through use of therapy only, therapy and monitoring, imaging and therapy, or therapy, imaging, and monitoring, and/or through use of focused, unfocused, or defocused ultrasound at various spatial and temporal energy settings. An exemplary method and system can be configured to produce regions of heating and damage by destroying the function of sebaceous glands within a user-specified treatment layer depth associated with the glands to be treated. In addition, an exemplary method and system can be configured to produce regions of heating and damage within the treatment layer in spatially defined patterns, rather than heating and destroying the entire volume of the target layer of tissue. Further, an exemplary method and system can be configured to specifically aim such regions of heating and damage within the treatment layer, to occur at the same location as the secretory portion of sebaceous glands.

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25 Claims, 23 Drawing Sheets



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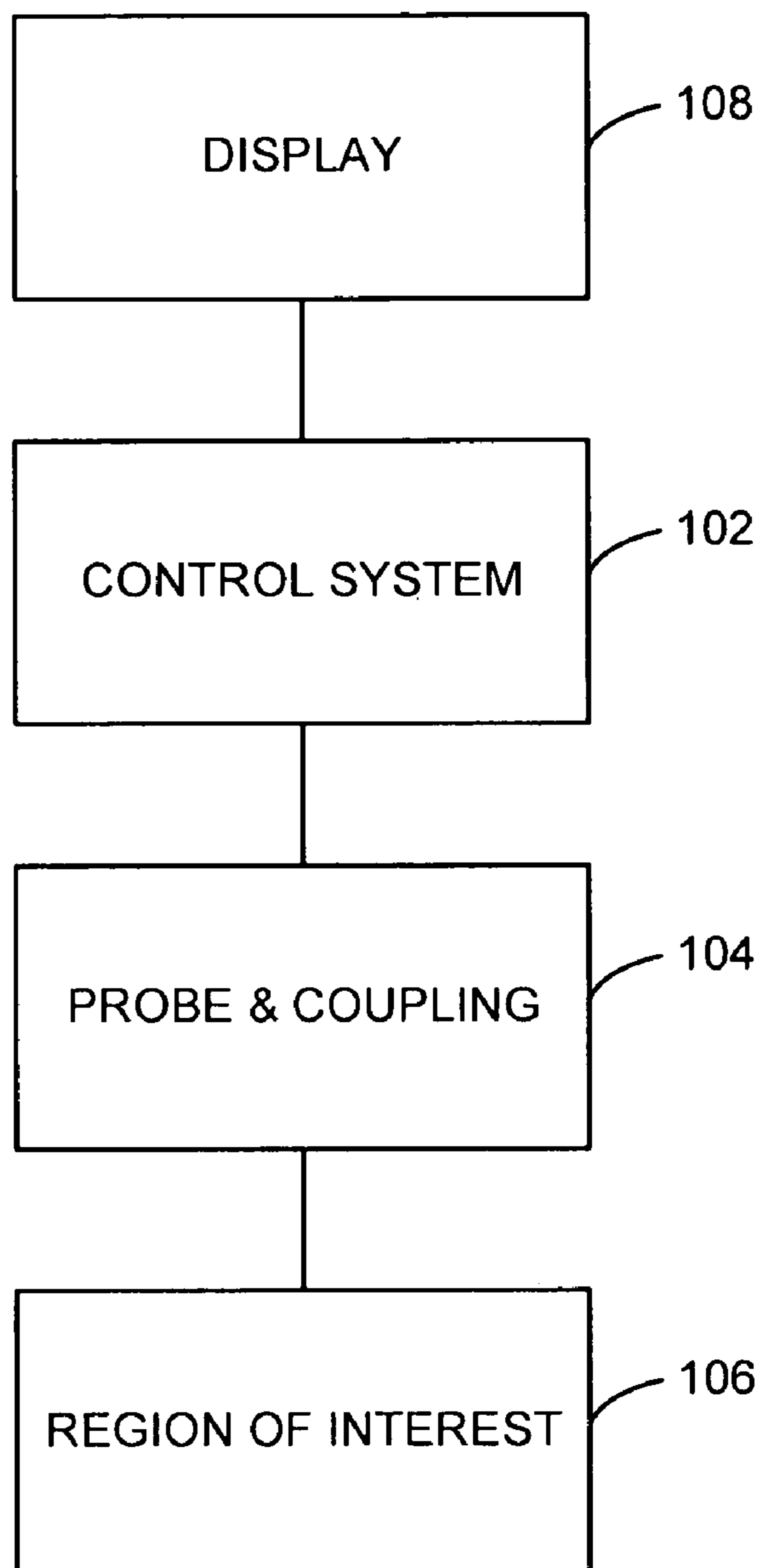



FIG. 1

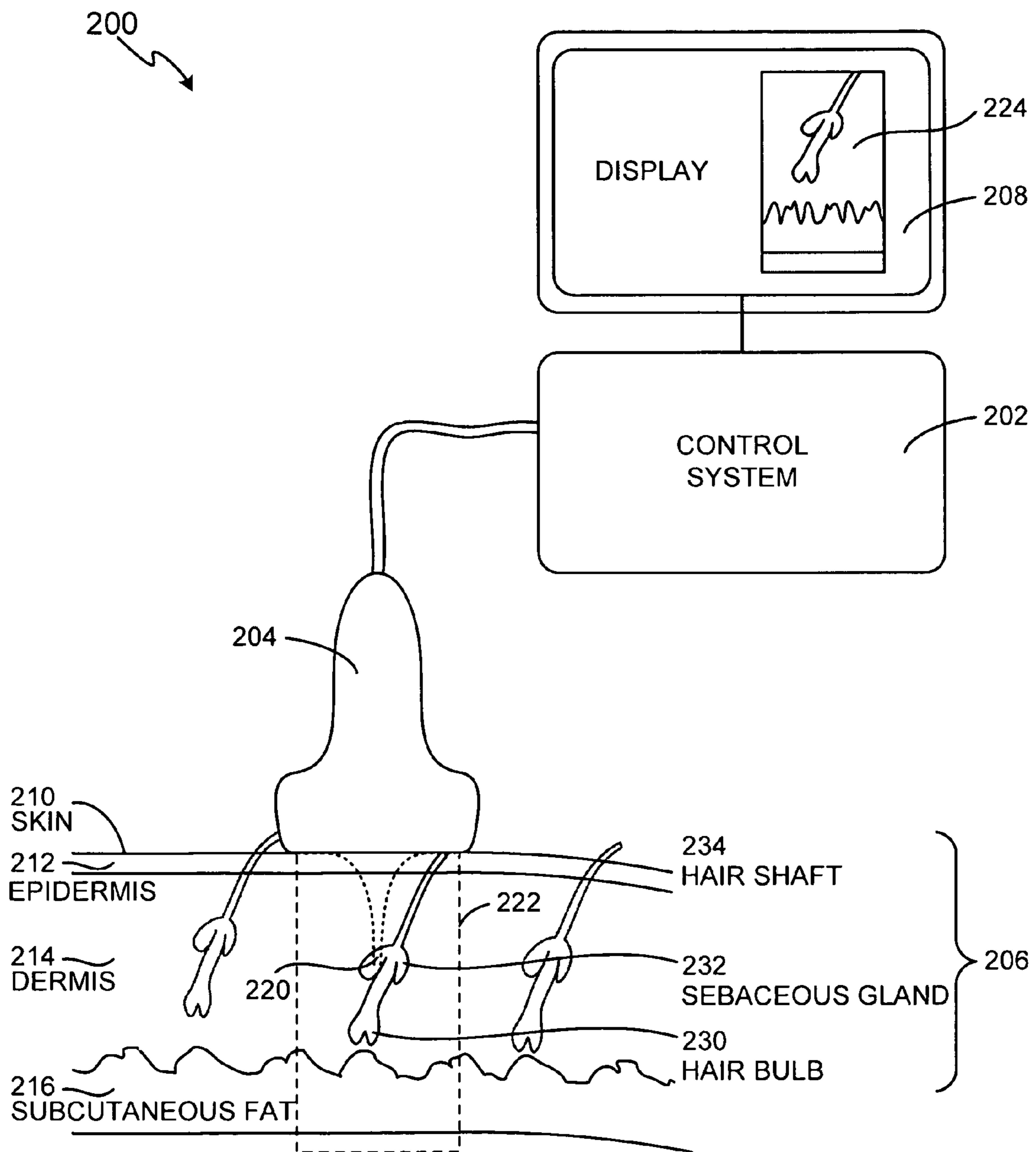


FIG. 2A

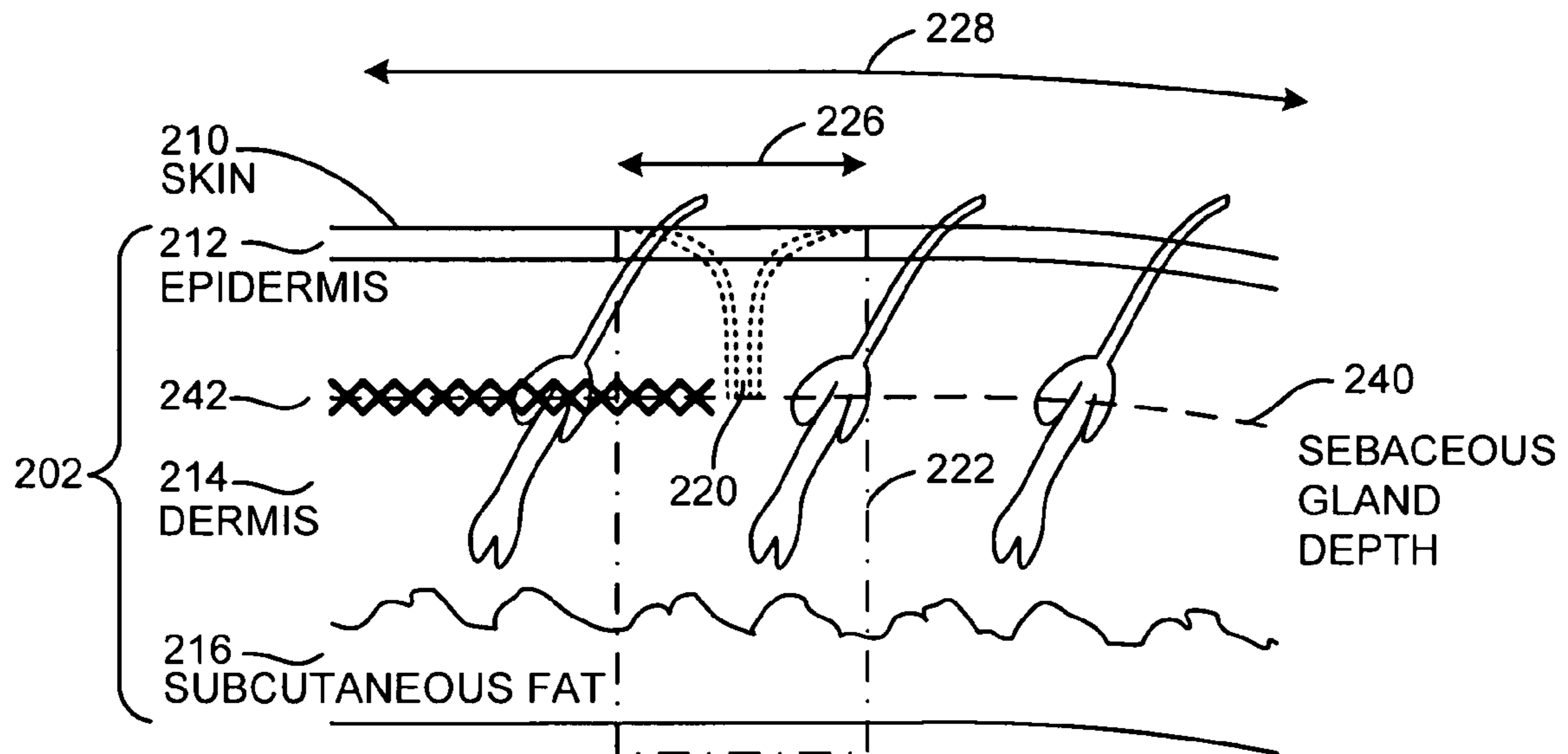


FIG. 2B

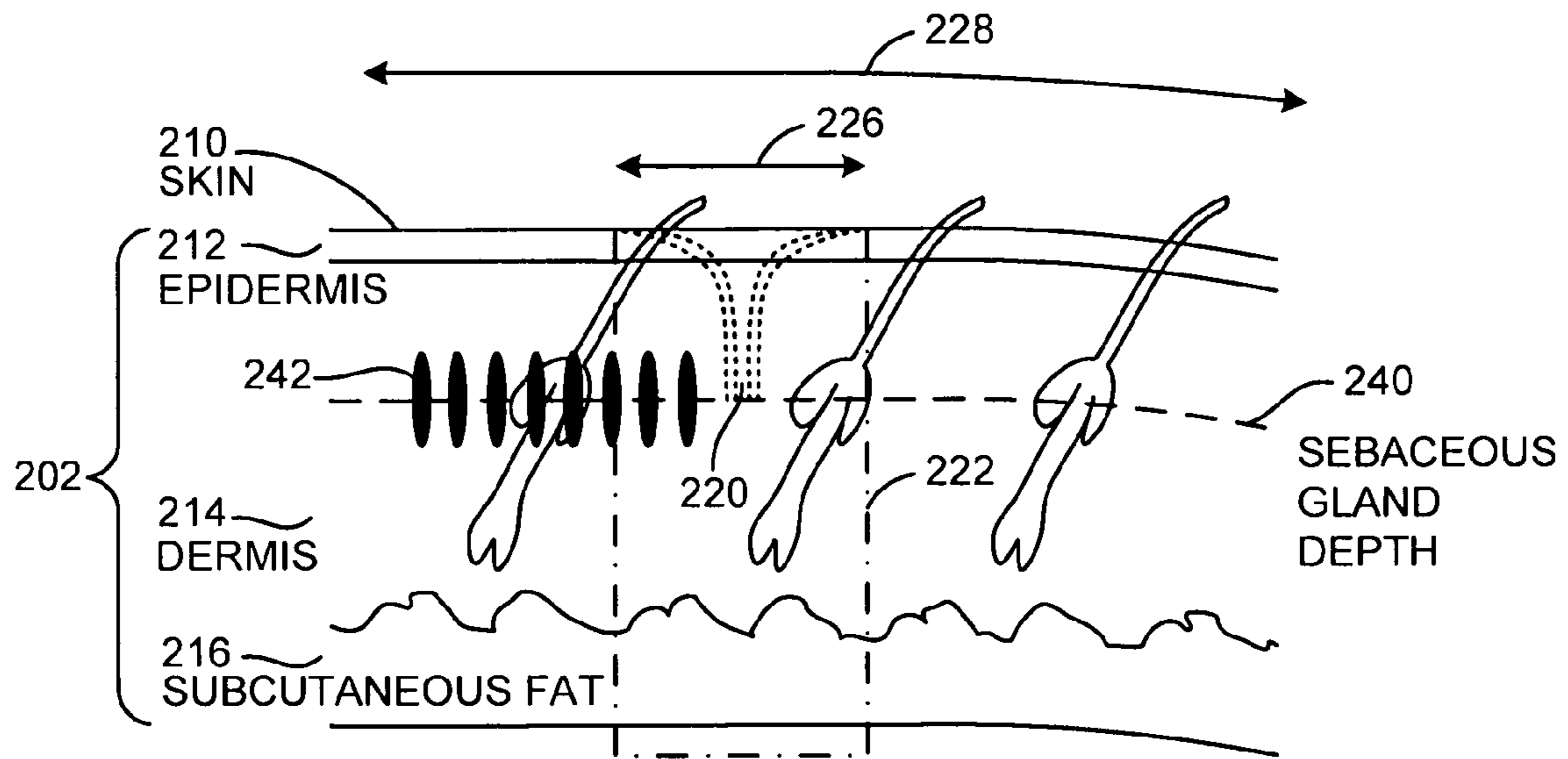


FIG. 2C

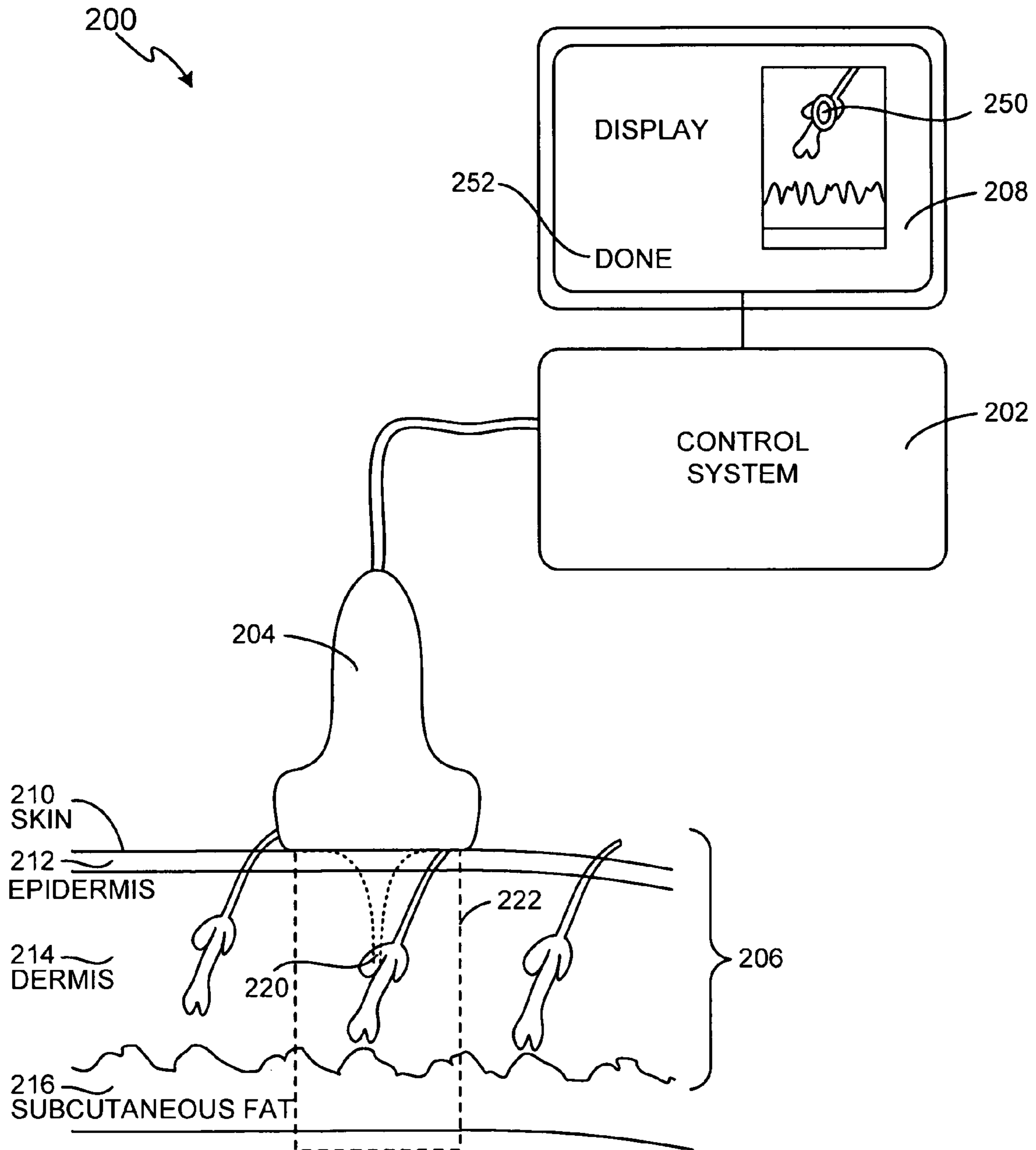


FIG. 2D

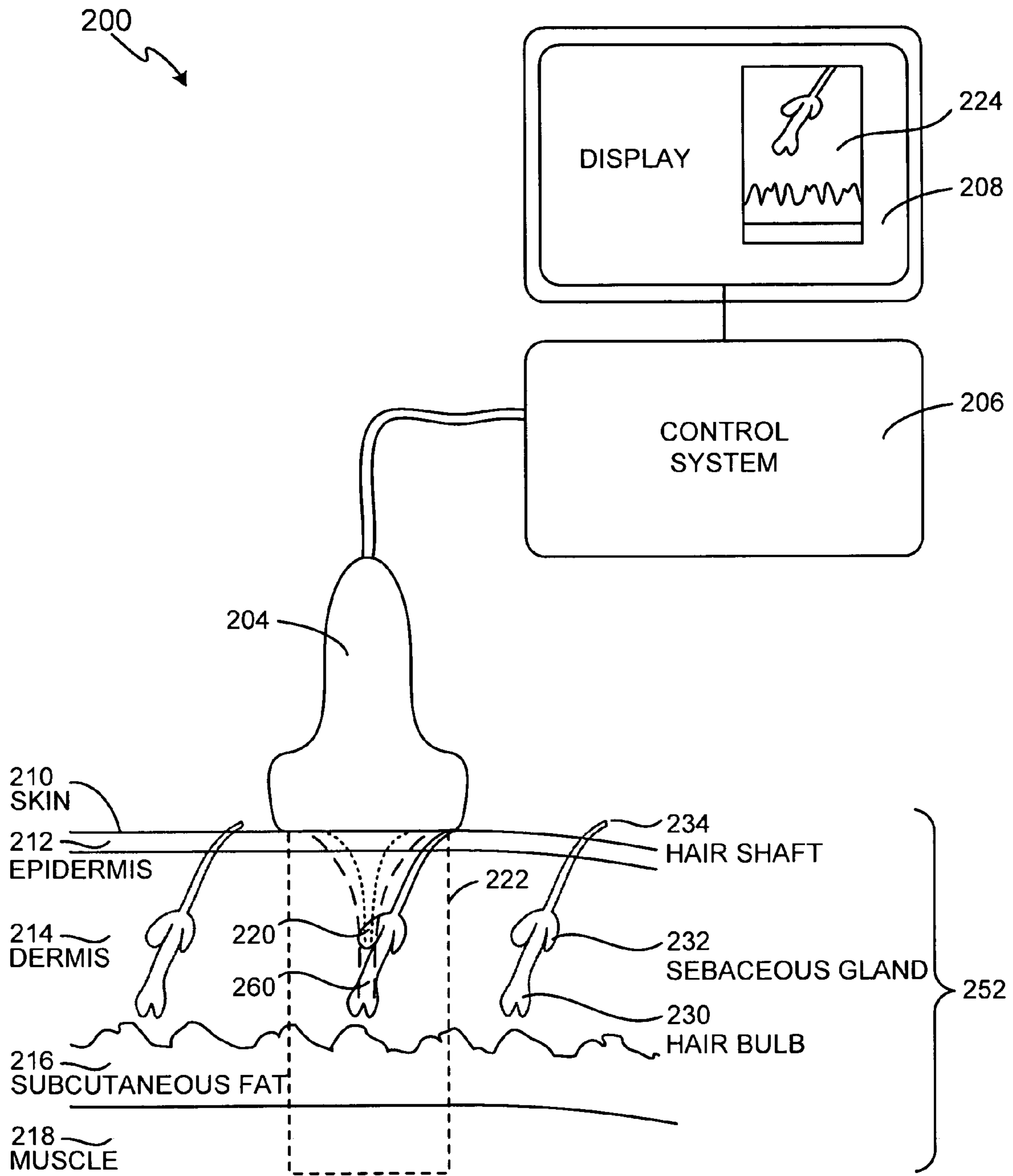


FIG. 2E

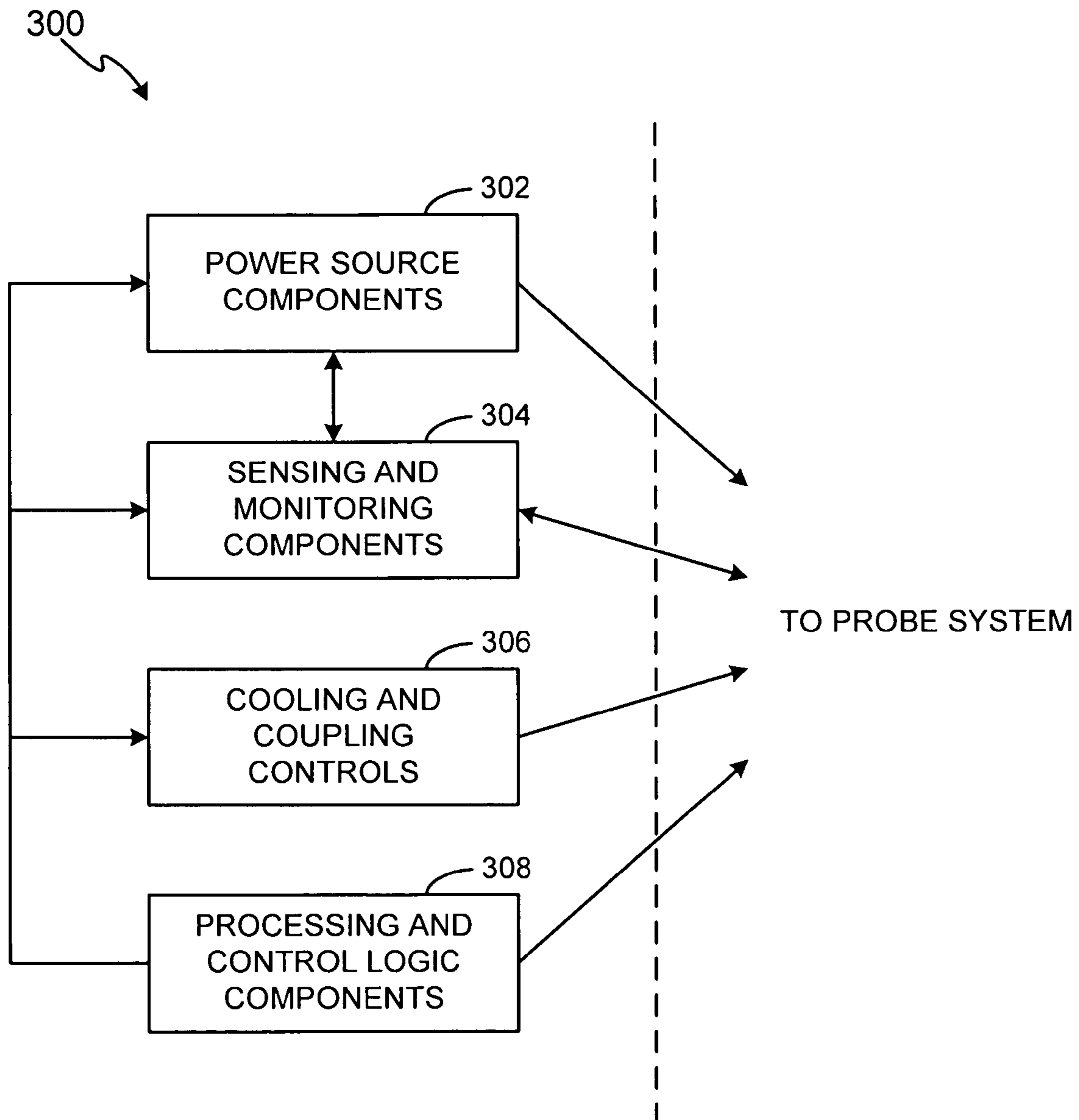


FIG. 3A

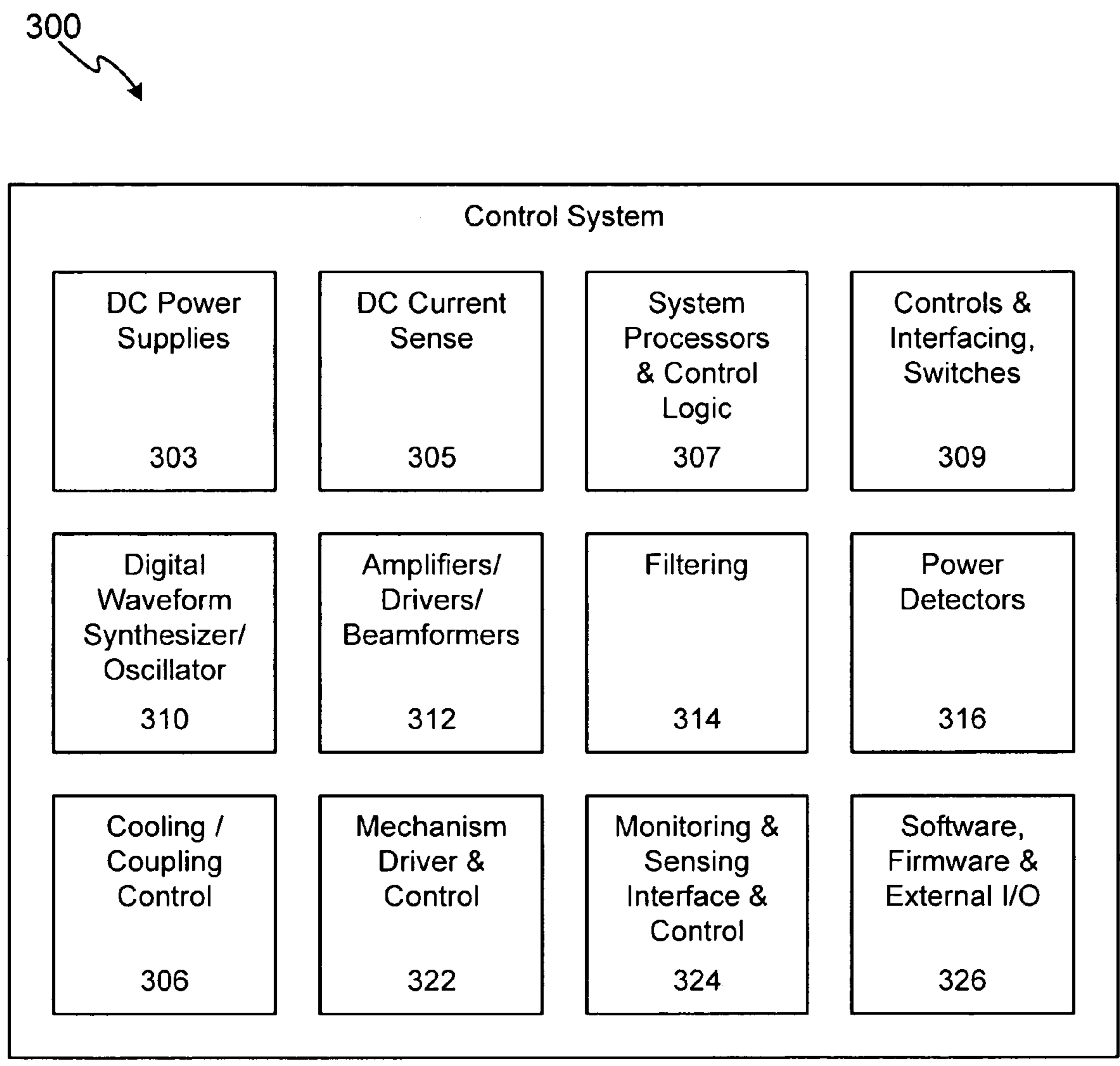


FIG. 3B

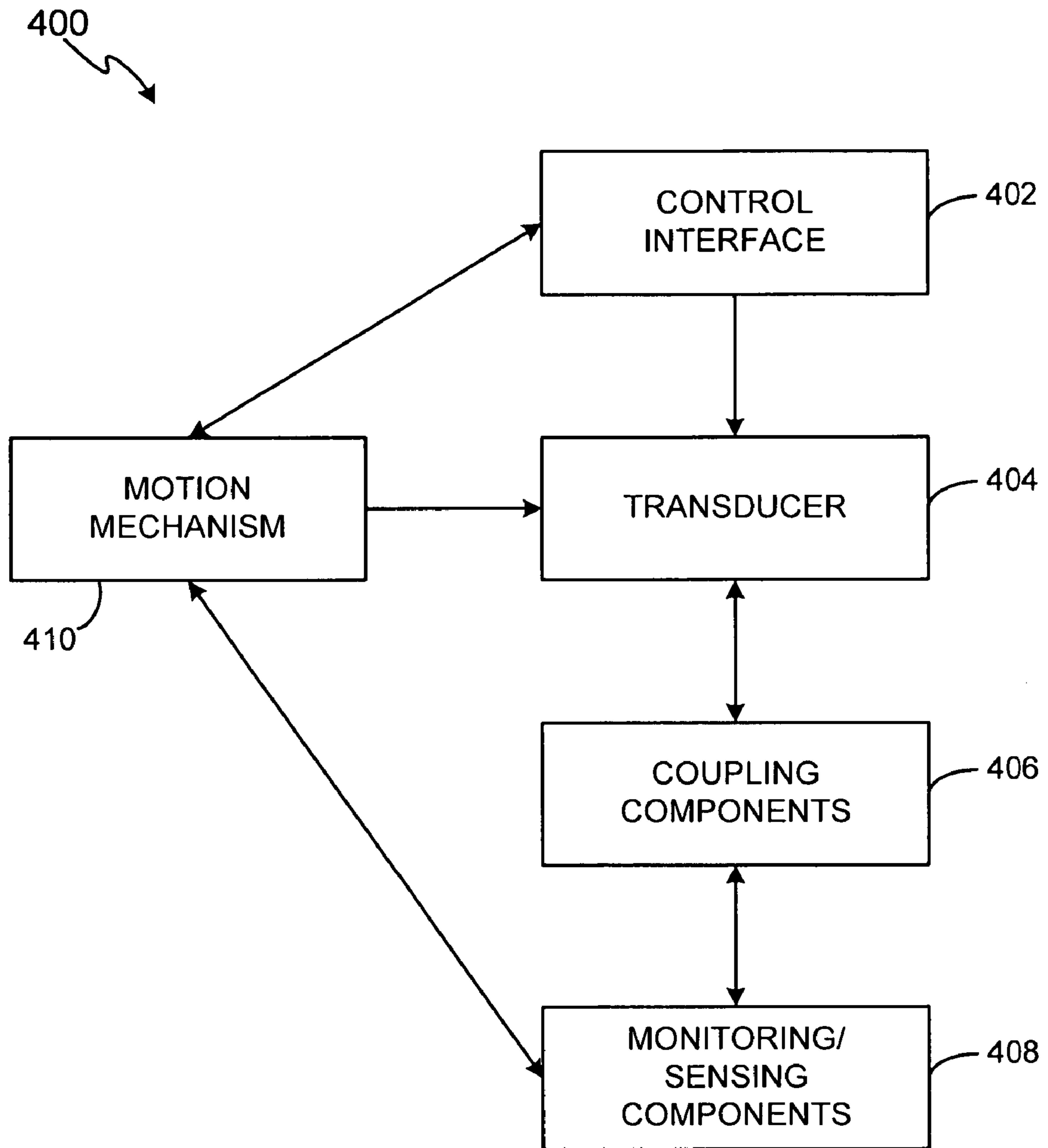


FIG. 4A

400 ↘

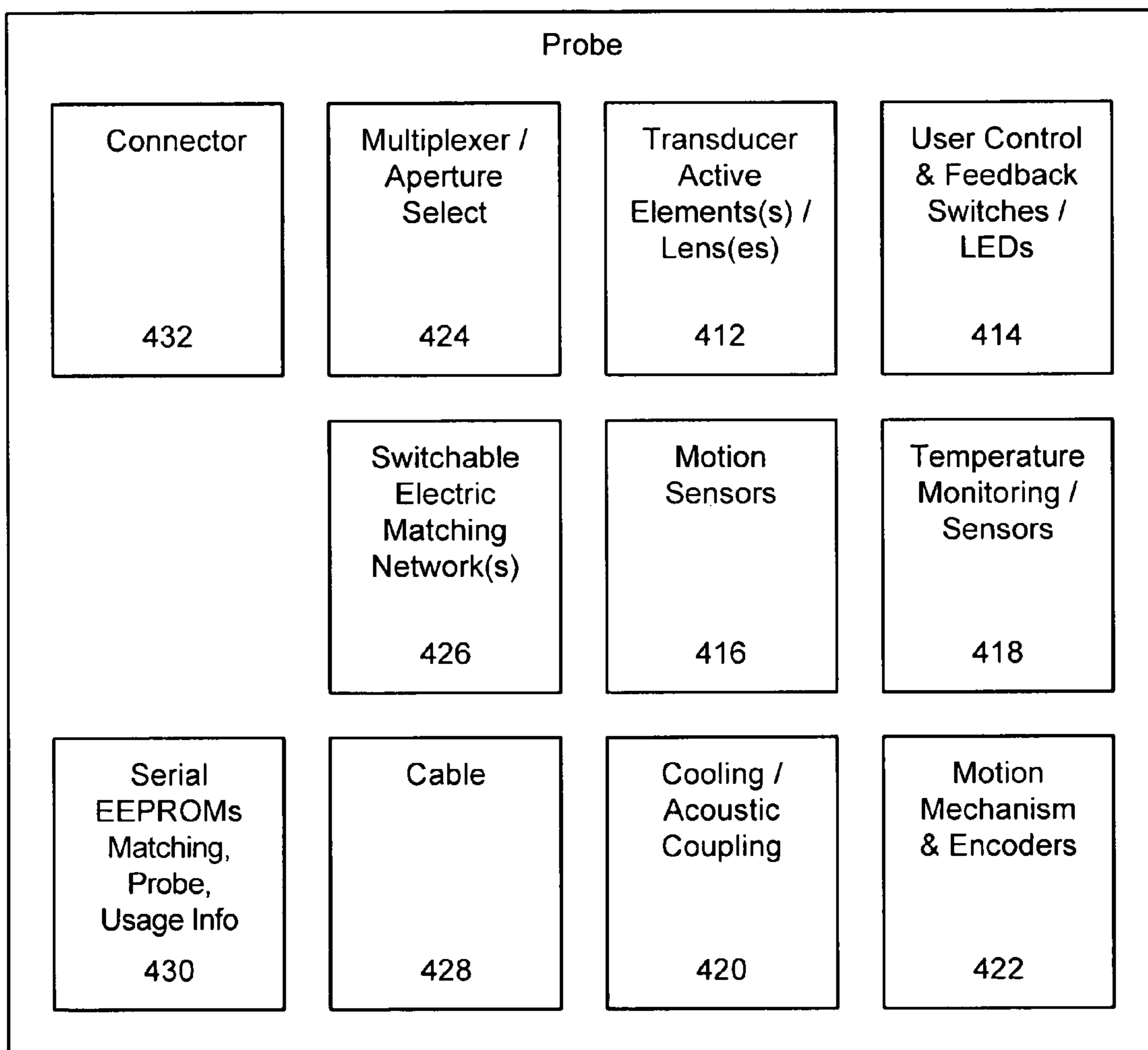


FIG. 4B

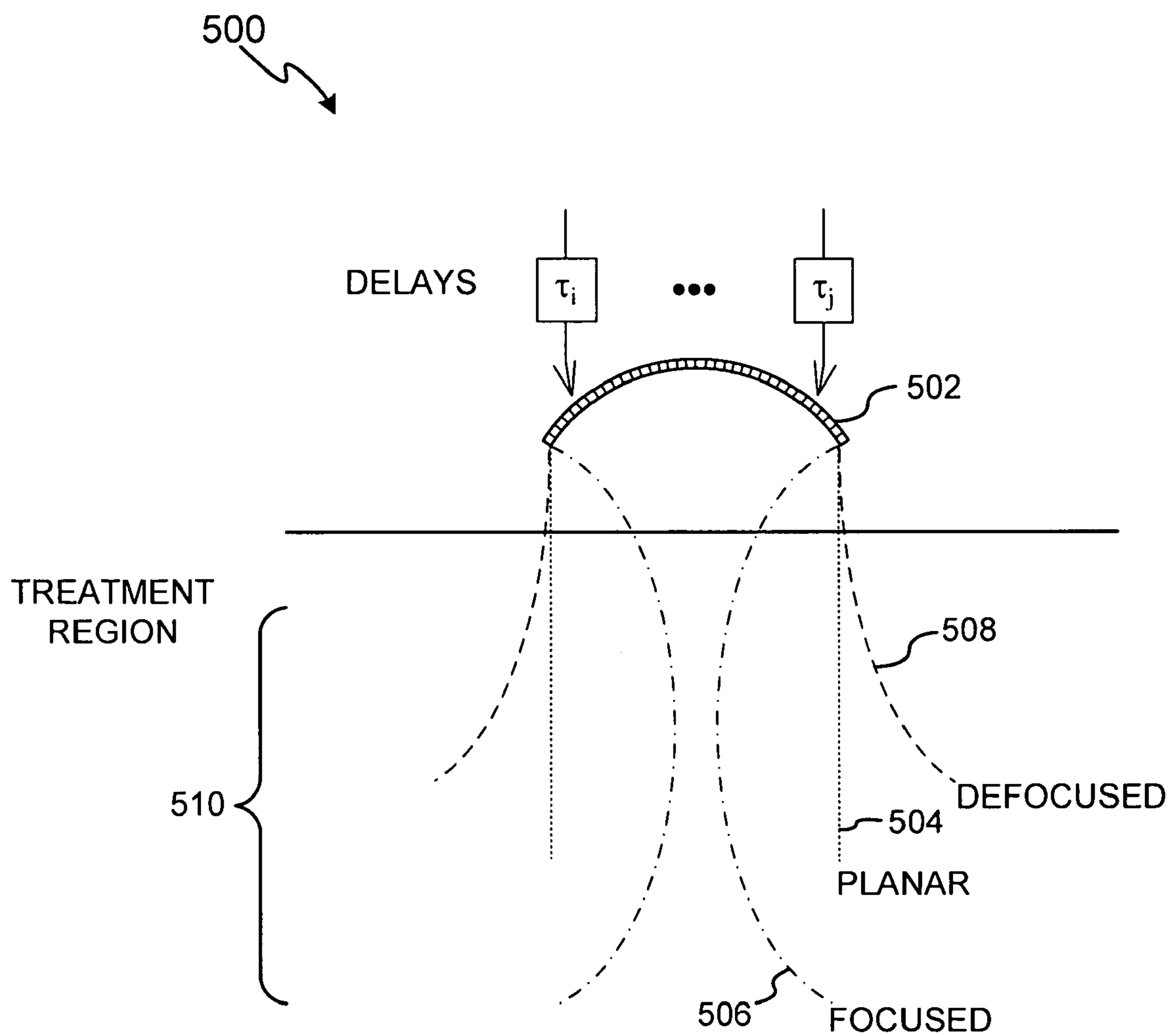


FIG. 5

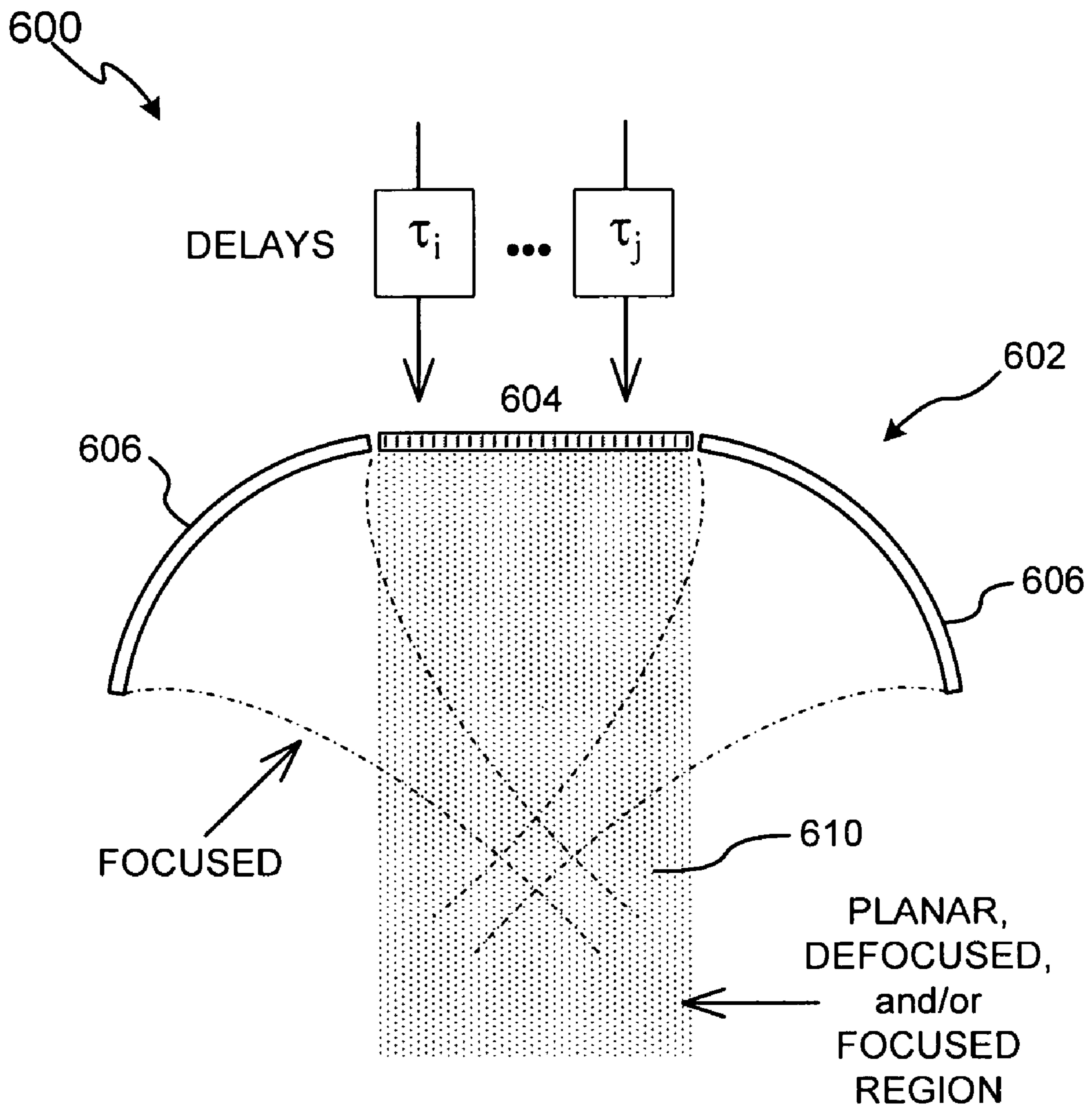


FIG. 6A

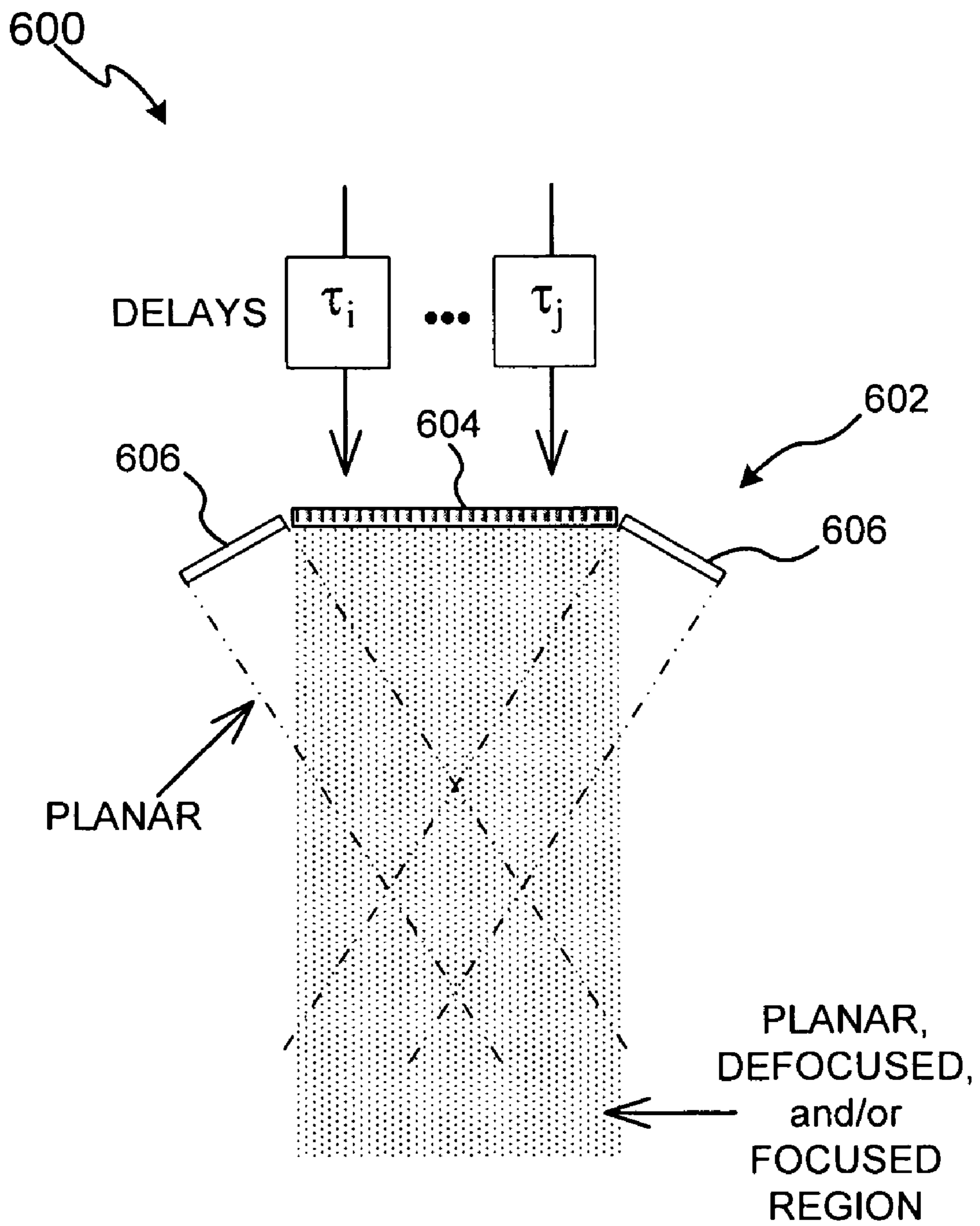


FIG. 6B

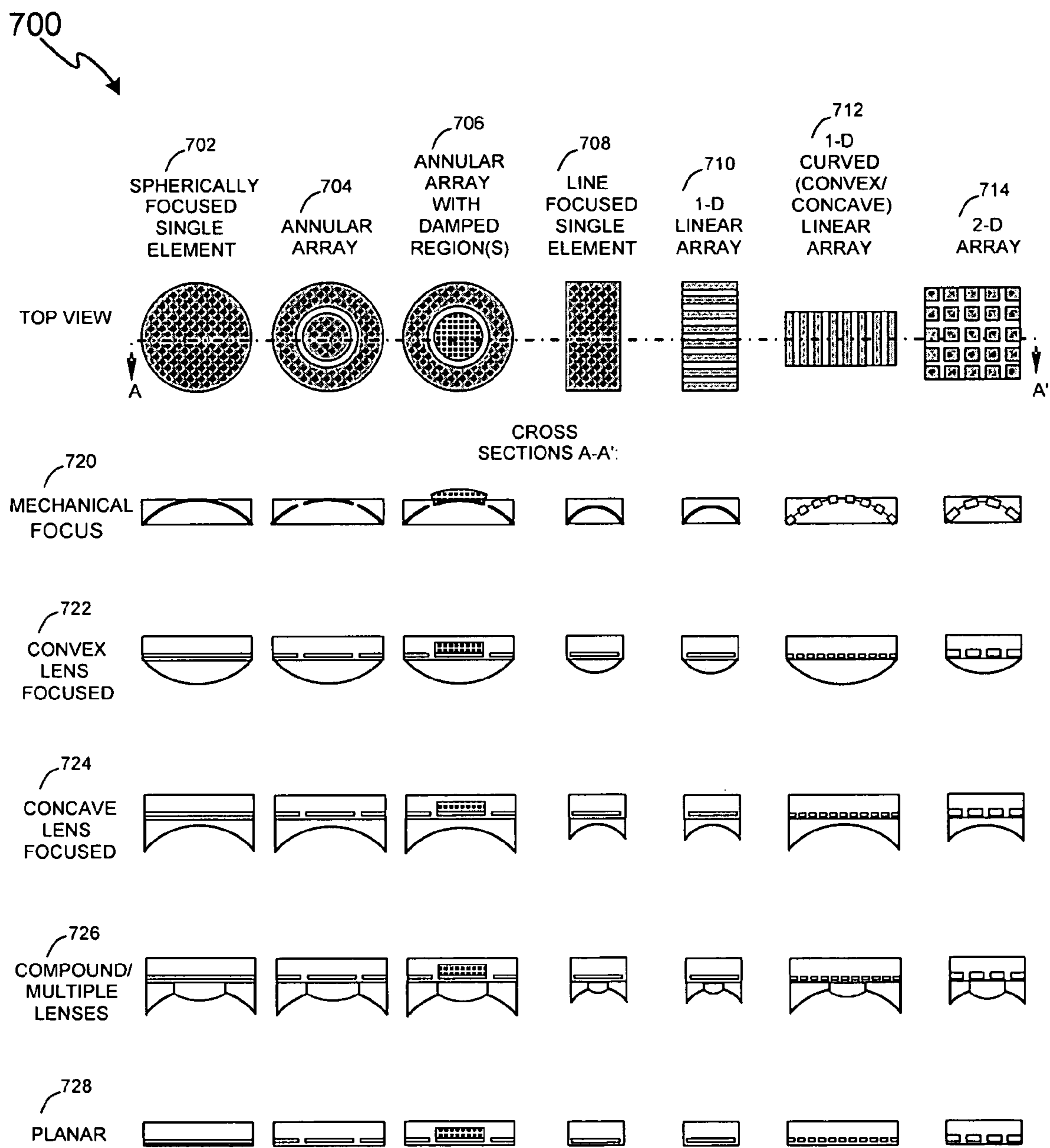


FIG. 7

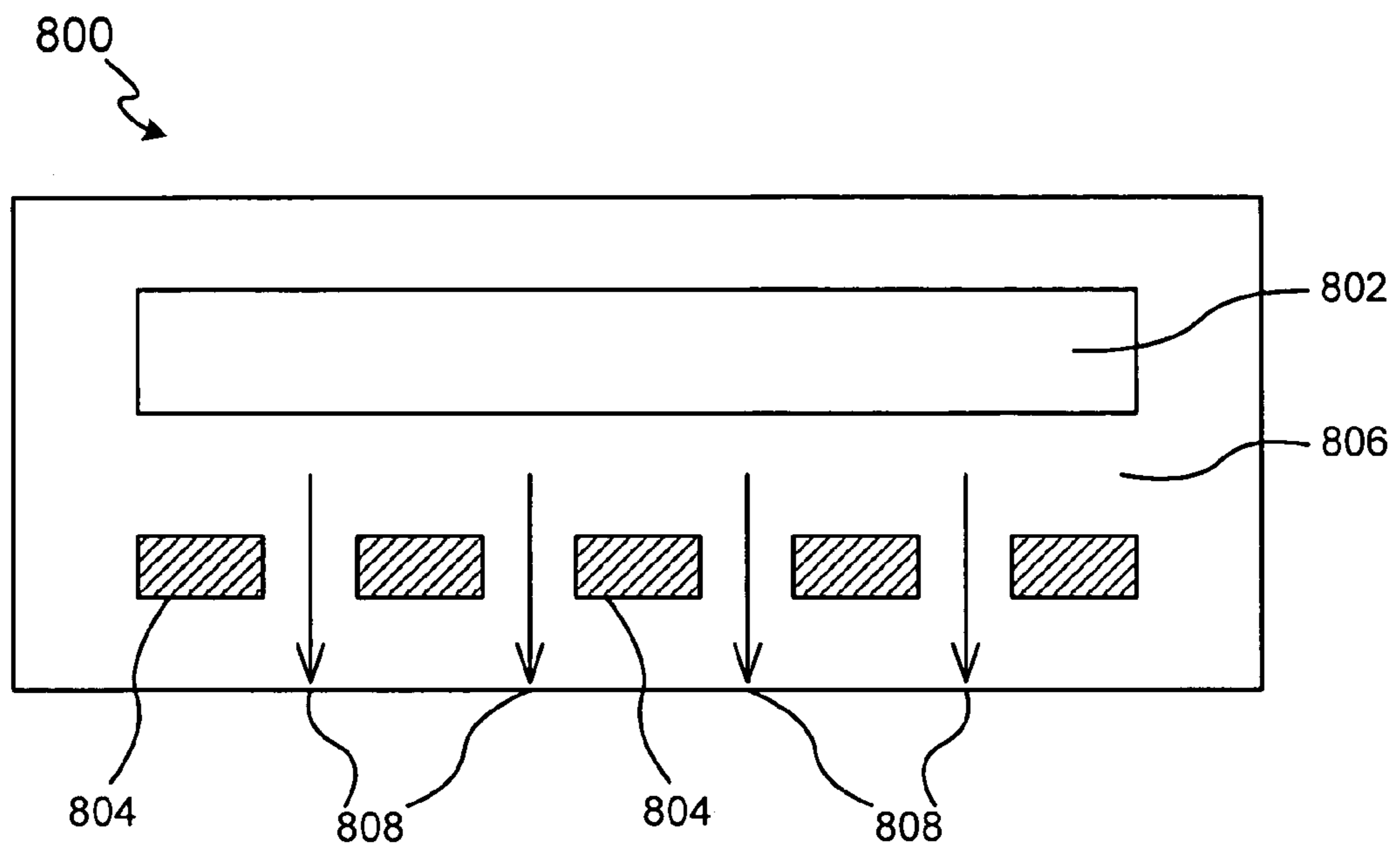


FIG. 8A

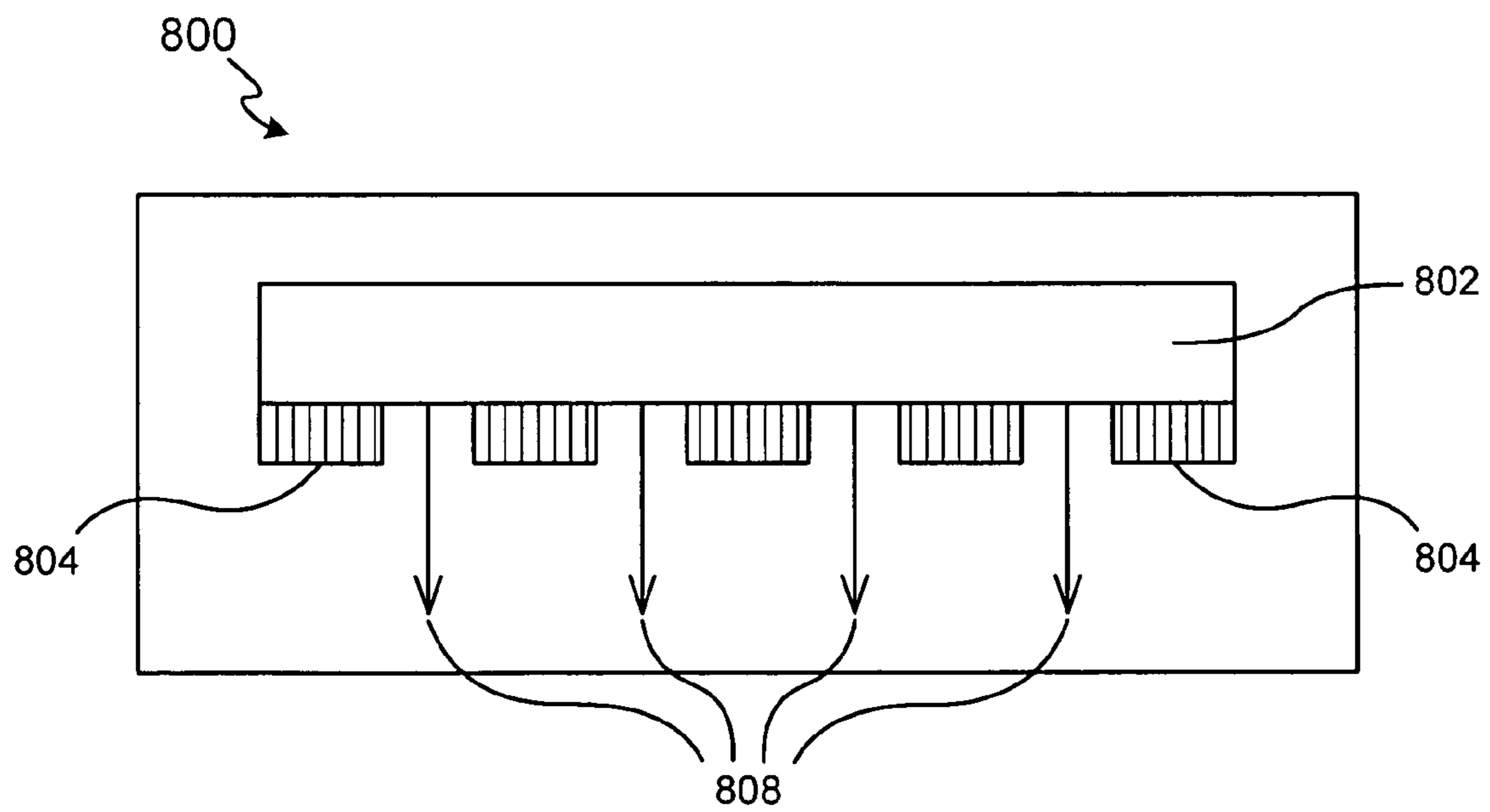


FIG. 8B

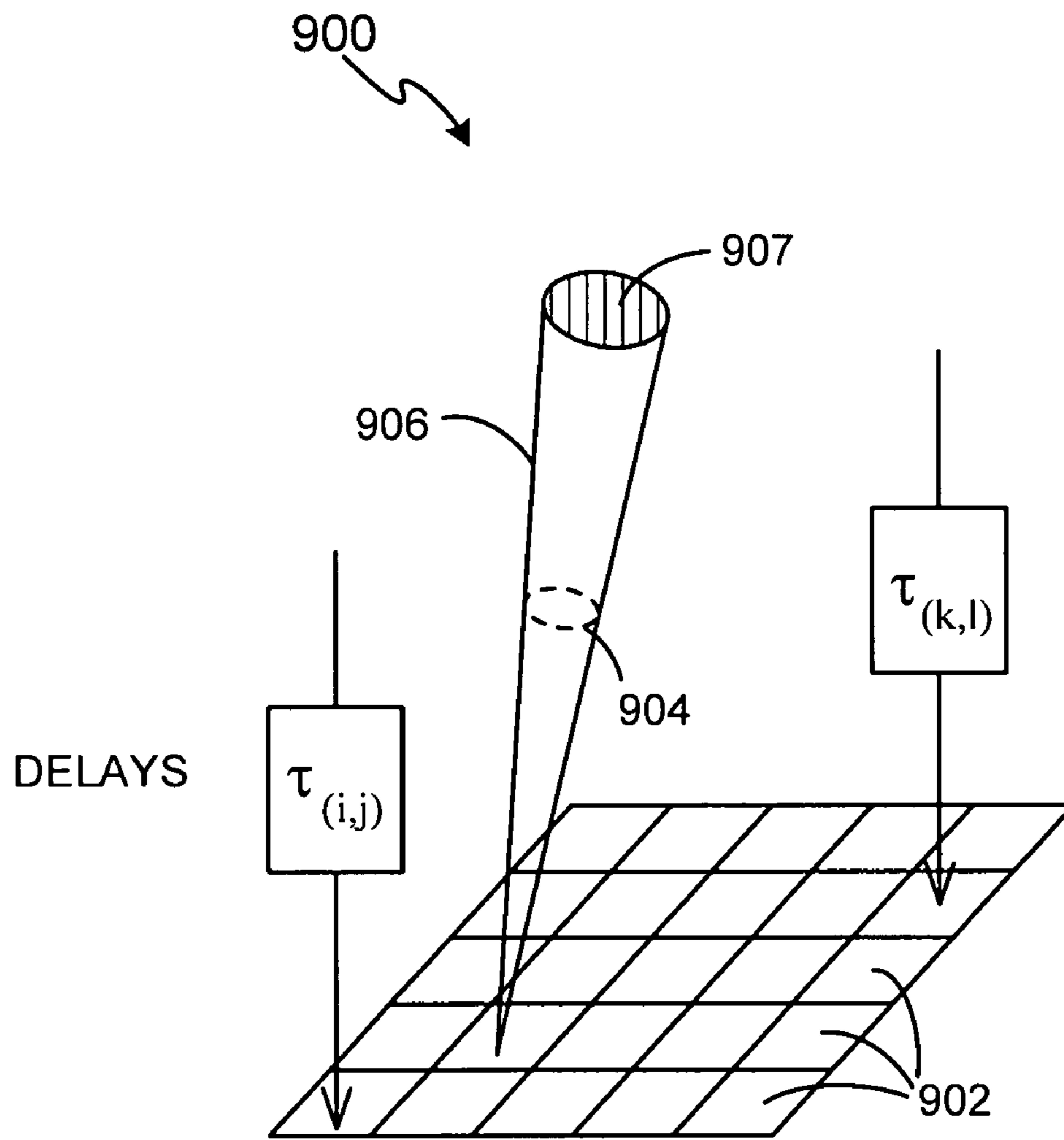


FIG. 9

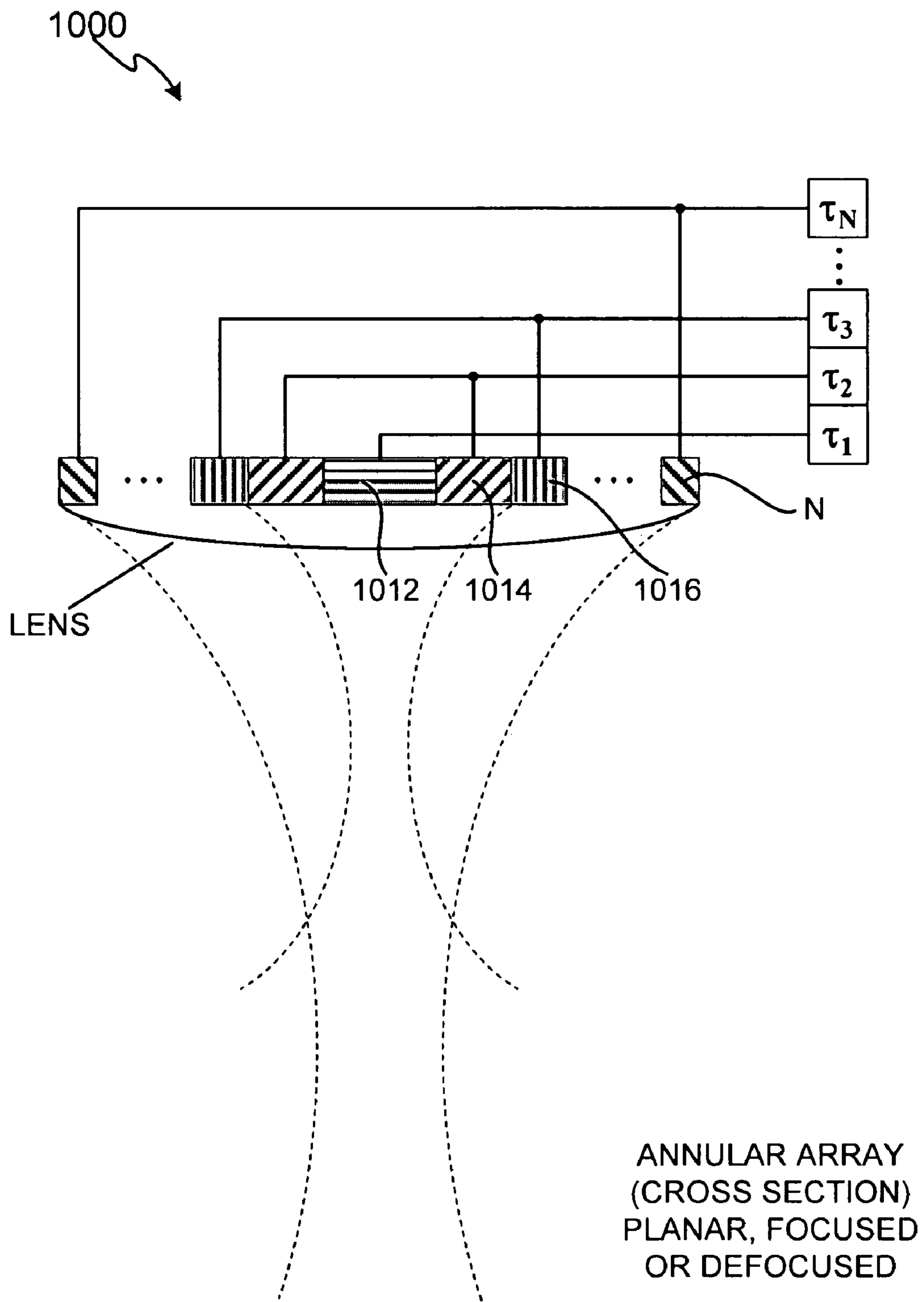
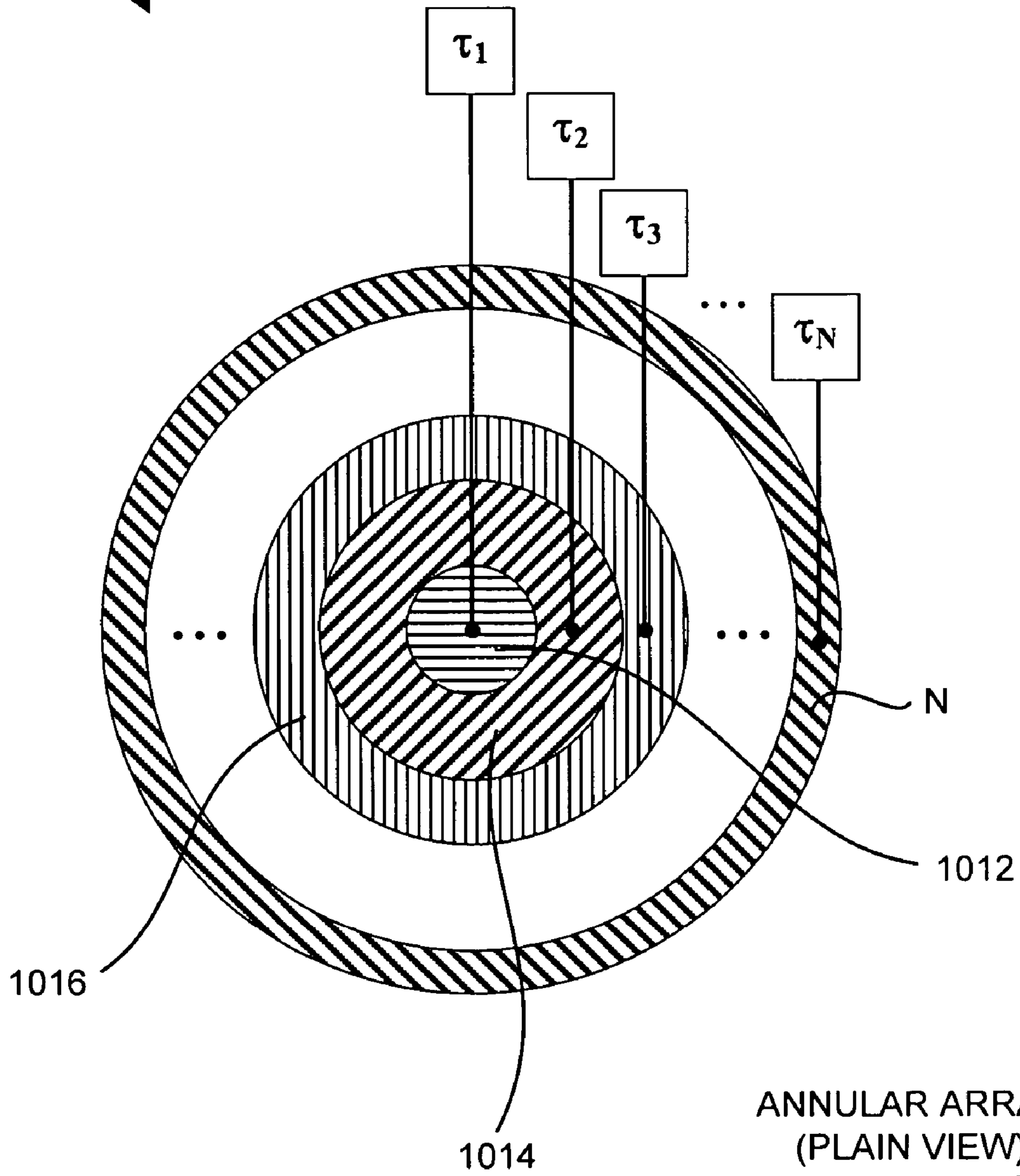


FIG. 10A

1000



ANNULAR ARRAY
(PLAIN VIEW)
PLANAR, FOCUSED
OR DEFOCUSED

FIG. 10B

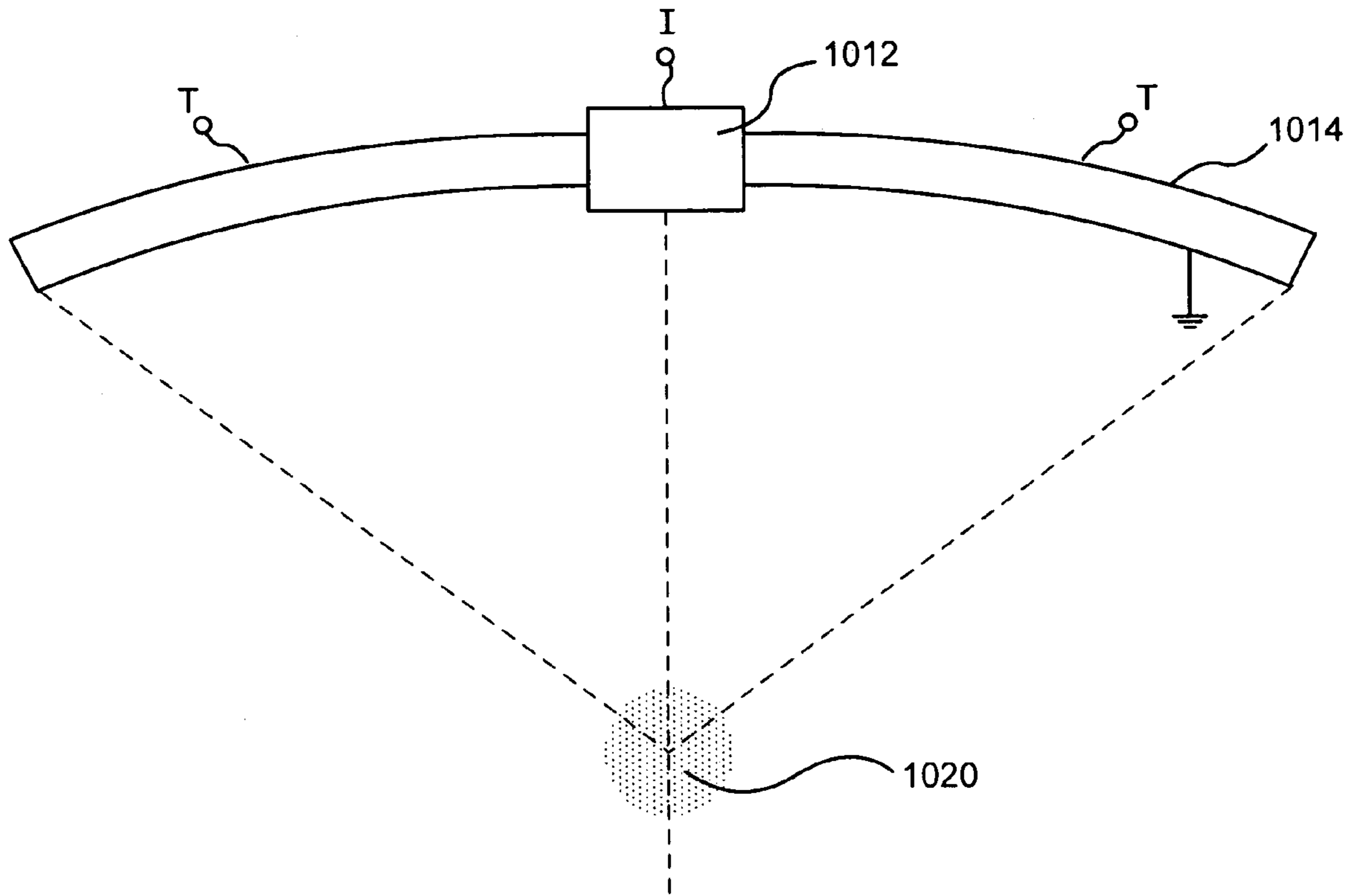


FIG. 10C

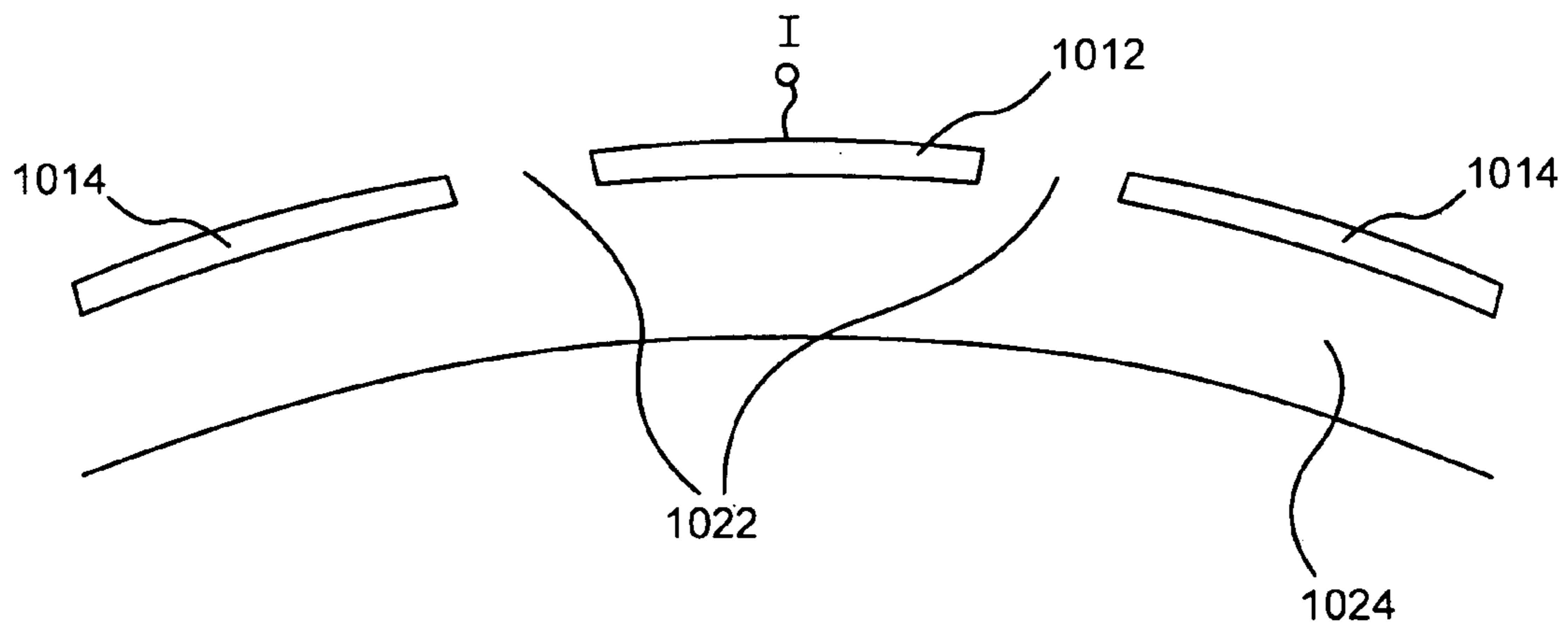


FIG. 10D

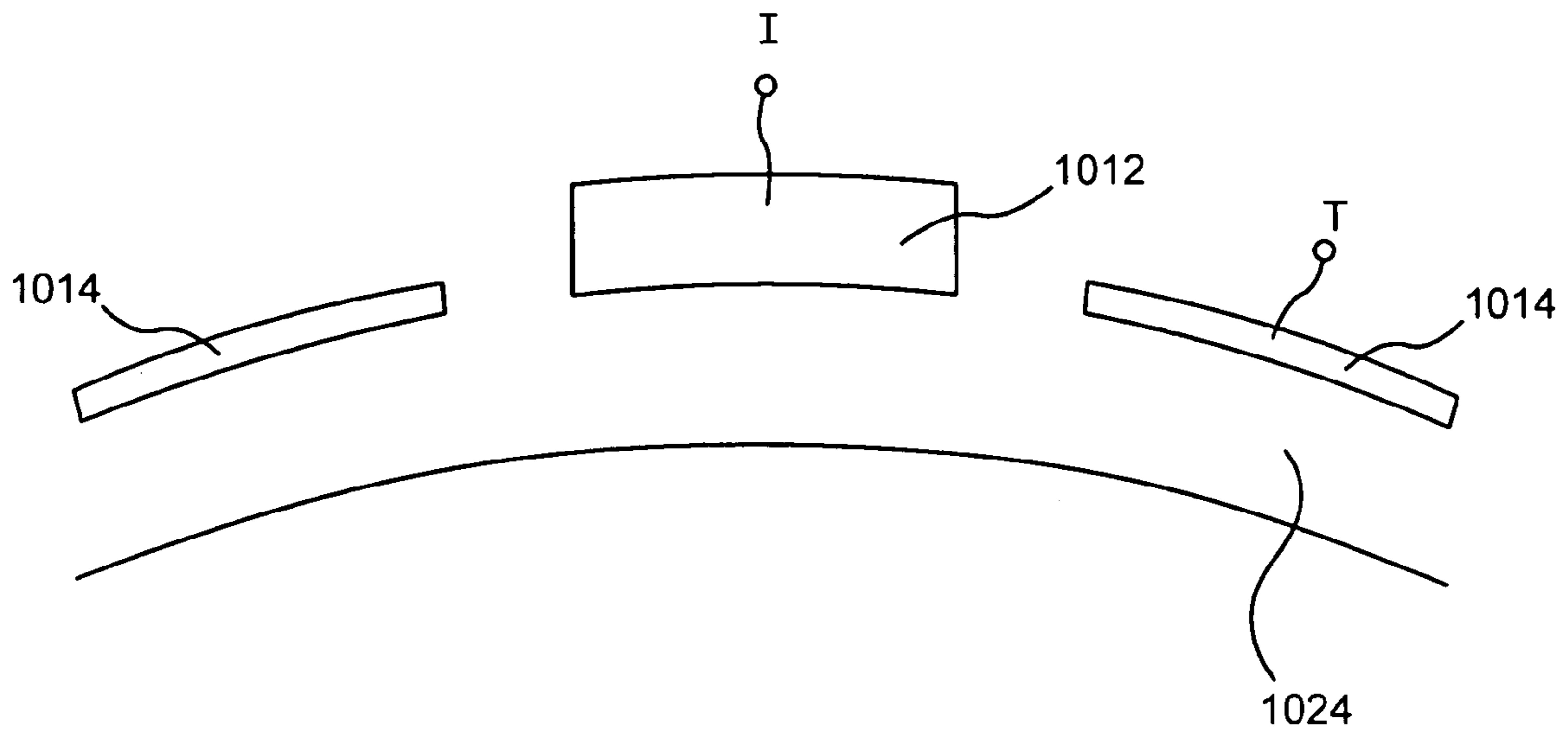


FIG. 10E

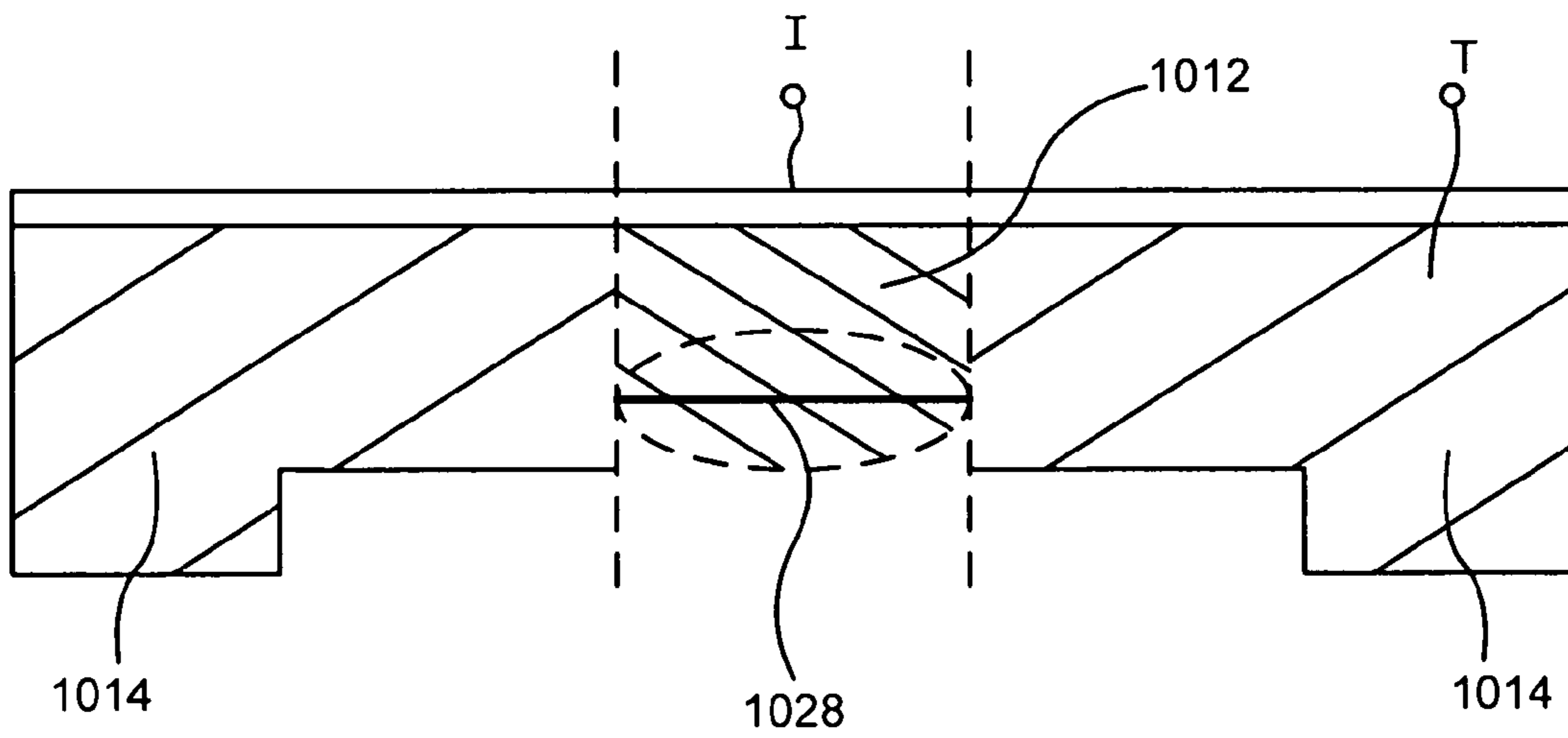


FIG. 10F

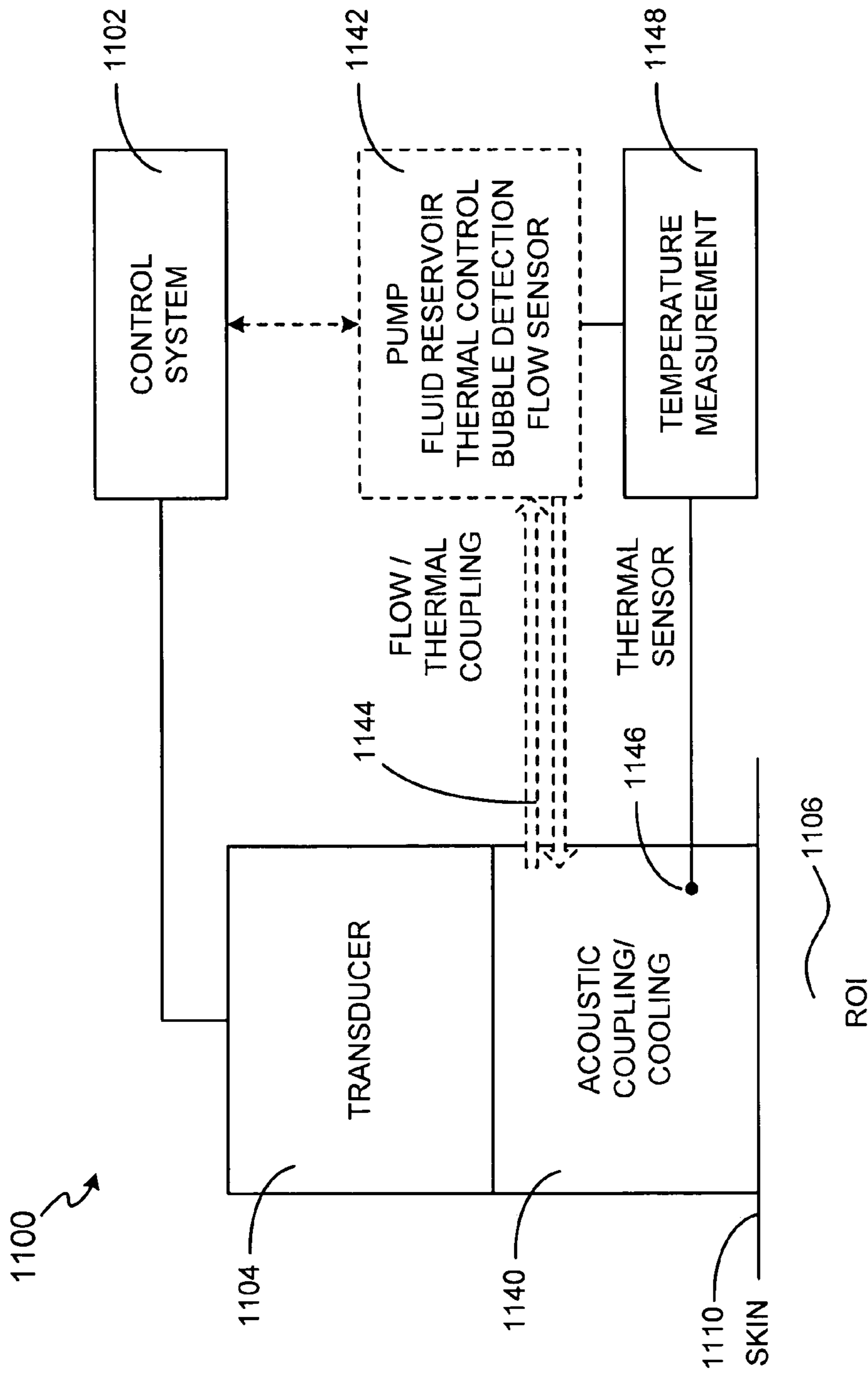


FIG. 11

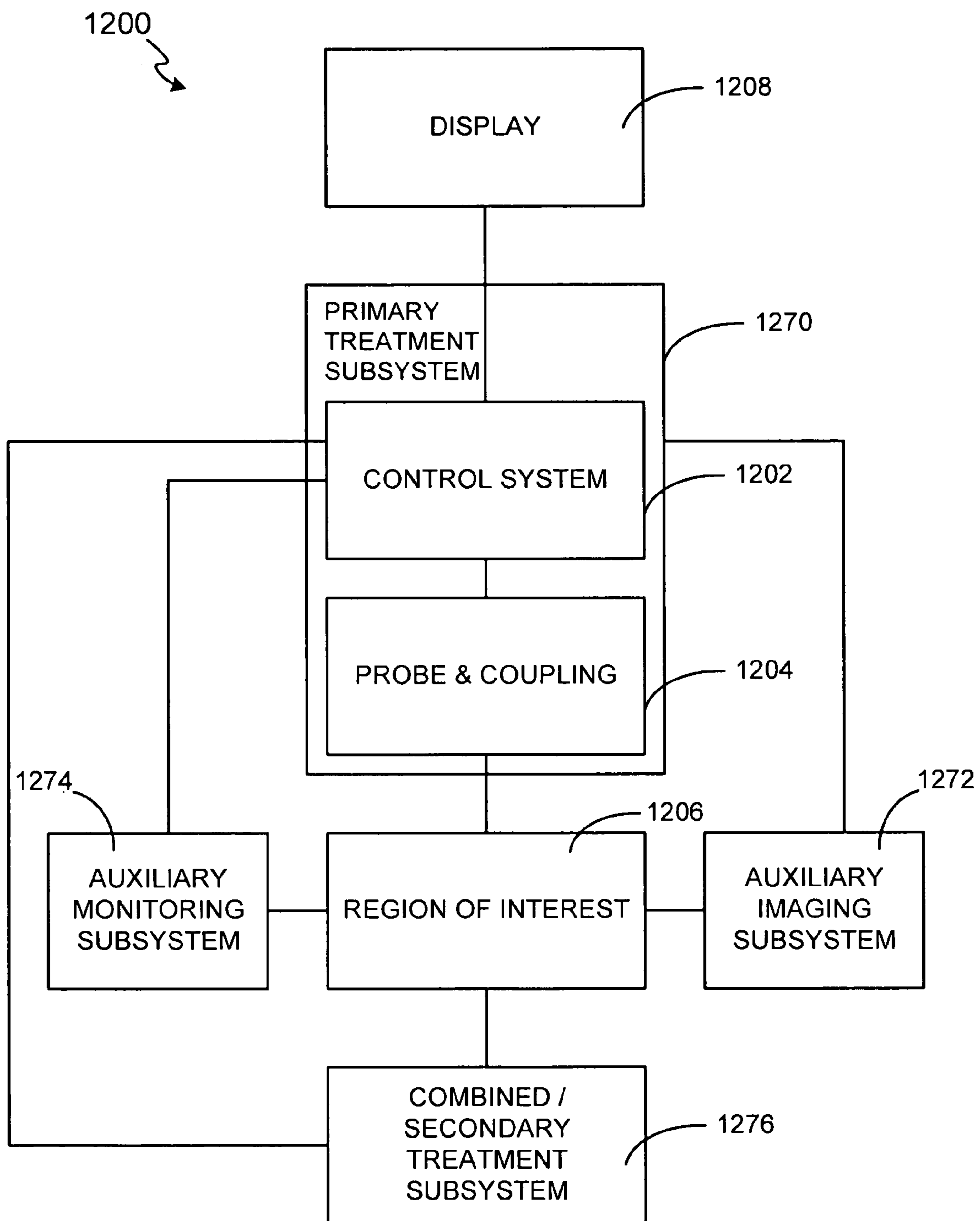


FIG. 12

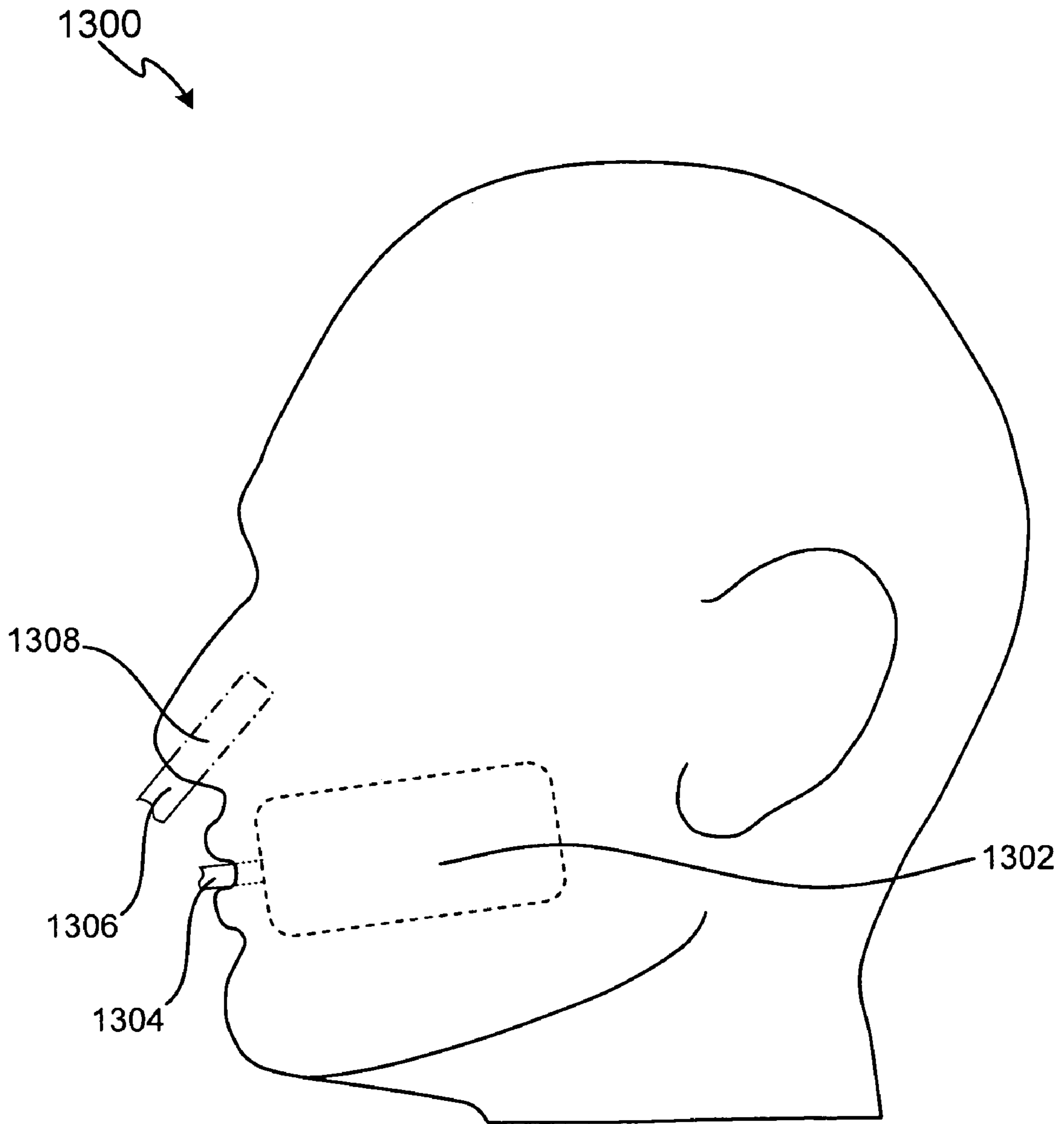


FIG. 13

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**METHOD AND SYSTEM FOR TREATING
ACNE AND SEBACEOUS GLANDS**CROSS-REFERENCE TO RELATED
APPLICATIONS

This Application claims priority to and benefit of U.S. Provisional Application No. 60/617,203, entitled "Method and System for Treating Acne and Sebaceous Glands", and filed on Oct. 7, 2004.

FIELD OF INVENTION

The present invention relates to ultrasound treatment systems, and in particular to a method and system for treating acne and sebaceous glands.

BACKGROUND OF INVENTION

Acne vulgaris is the most common skin disorder. Acne causes temporary and permanent disfigurement. Acne typically appears on the face, back and/or chest at the onset of adrenarchy, i.e. when sex hormone activity increases in both boys and girls near puberty. Acne is a disorder of hair follicles, in which a plug forms within the outflow tract of the hair follicle. Sebum, an oily product of sebaceous glands attached to each hair follicle, and cellular debris builds in the plug. Inflammation and often rupture of the hair follicles ensues, leading to gross inflammation, pus (a "whitehead"), pain, bleeding, and/or eventually scarring. If the acne lesion consists of an accumulated unruptured plug within the hair follicle, a "blackhead" forms. If the follicle ruptures superficially, a small pustule forms that often heals after a few weeks without scarring. If the follicle ruptures within the mid or deep dermis, a painful cystic abscess forms. Cystic acne usually heals with permanent and disfiguring scars.

The exact pathophysiology of acne is complex and is not fully understood. However, several basic elements are necessary to produce an acne lesion, and acne therapies are based on attacking one or more of these basic elements. First, an active sebaceous gland is necessary. The most potent treatments for acne are oral retinoids such as retinoic acid (Accutane), which inhibit sebaceous gland function. Sebaceous gland activity is driven by androgen and other sex steroid hormones. Women often experience cycle-dependent acne that may respond to treatment with birth control pills containing low amounts of progestins. Second, a plug must form in the outflow tract of the follicle, called the infundibulum. Bacteria, particularly *Propionibacteria acnes* (*P acnes*) that digest sebum and follicular debris, contribute to plugging. Topical retinoids, mild acids and benzoyl peroxide are used as treatments to decrease follicular plugging. Antibiotics effective against *P acnes* are given either topically or orally; the prevalence of antibiotic-resistant *P acnes* is increasing. Third, inflammation is part of the process that breaks down the wall of a follicle containing plugs, leading to rupture of the follicle with release of irritating materials into the skin, abscess formation, and scarring. Anti-inflammatory agents including some antibiotics are helpful in treating acne.

The most potent treatment for acne at present is oral retinoid therapy. Unfortunately, this is a toxic and teratogenic treatment. Unplanned pregnancies in women taking Accutane lead to a high rate of fetal malformations. An aggressive program to prevent this in the US was implemented, but has failed to prevent the problem. Systemic retinoid treatment also causes major side effects including extreme dryness during treatment, risk of hepatitis, bone changes, mood changes,

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and others. The high effectiveness and high toxicity of oral retinoids for treatment of cystic acne strongly suggests that an alternative treatment that targets sebaceous glands is needed.

SUMMARY OF INVENTION

A method and system for ultrasound treatment of acne and sebaceous glands are provided. An exemplary method and system are configured for targeted treatment of sebaceous glands in various manners, such as through use of therapy only, therapy and monitoring, imaging and therapy, or therapy, imaging, and monitoring. Targeted therapy of sebaceous glands can be provided through use of focused, unfocused, or defocused ultrasound at various spatial and temporal energy settings.

An exemplary method and system are configured to produce regions of heating and damage in various manners. For example, an exemplary method and system can be configured to produce regions of heating and damage by destroying the function of sebaceous glands within a user-specified treatment layer depth associated with the glands to be treated. In addition, an exemplary method and system can be configured to produce regions of heating and damage within the treatment layer in spatially defined patterns, rather than heating and destroying the entire volume of the target layer of tissue. Further, an exemplary method and system can be configured to specifically aim such regions of heating and damage within the treatment layer, to occur at the same location as the secretory portion of sebaceous glands.

In accordance with an exemplary embodiment, an exemplary treatment system comprises a control system, an imaging/therapy probe, and display system. The imaging/therapy probe can comprise various probe and/or transducer configurations. For example, the probe can be configured for a combined dual-mode imaging/therapy transducer, coupled or co-housed imaging/therapy transducers, a therapy probe, or simply a therapy probe and an imaging probe. The control system and display system can also comprise various configurations for controlling probe and system functionality, including for example a microprocessor with software and a plurality of input/output devices, a system for controlling electronic and/or mechanical scanning and/or multiplexing of transducers, a system for power delivery, systems for monitoring, systems for sensing the spatial position of the probe and/or transducers, and systems for handling user input and recording treatment results, among others.

In accordance with an exemplary embodiment, ultrasound imaging can be used for safety purposes, namely, to avoid injuring vital structures. In accordance with another exemplary embodiment, ultrasound imaging can be used to define the position of a sebaceous gland and/or the depth of sebaceous glands over a region of interest. Such glands can be seen lying along hair follicles and their image may be further enhanced via signal and image processing.

In accordance with an exemplary embodiment, ultrasound therapy via focused, unfocused, or defocused ultrasound, delivered via an array of foci or array of treatment zones, a locus of foci or locus treatment zones, a line focus or linear treatment zone, a surface or volume focus or surface or volume treatment zone, and/or diffraction patterns from single element, multiple elements, annular array, one-, two-, or three-dimensional arrays, broadband transducers, and/or combinations thereof, with or without lenses, acoustic components, mechanical and/or electronic focusing or defocusing are utilized to treat sebaceous glands at fixed and/or variable depth or dynamically controllable depths and positions.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter of the invention is particularly pointed out in the concluding portion of the specification. The invention, however, both as to organization and method of operation, may best be understood by reference to the following description taken in conjunction with the accompanying drawing figures, in which like parts may be referred to by like numerals:

FIG. 1 illustrates a block diagram of a treatment system in accordance with an exemplary embodiment of the present invention;

FIGS. 2A-2E illustrates schematic diagrams of ultrasound treatment systems configured to treat the sebaceous gland via direct targeting of heating and damage within the treatment layer in accordance with various exemplary embodiments of the present invention;

FIGS. 3A and 3B illustrate block diagrams of an exemplary control system in accordance with exemplary embodiments of the present invention;

FIGS. 4A and 4B illustrate block diagrams of an exemplary probe system in accordance with exemplary embodiments of the present invention;

FIG. 5 illustrates a cross-sectional diagram of an exemplary transducer in accordance with an exemplary embodiment of the present invention;

FIGS. 6A and 6B illustrate cross-sectional diagrams of an exemplary transducer in accordance with exemplary embodiments of the present invention;

FIG. 7 illustrates exemplary transducer configurations for ultrasound treatment in accordance with various exemplary embodiments of the present invention;

FIGS. 8A and 8B illustrate cross-sectional diagrams of an exemplary transducer in accordance with another exemplary embodiment of the present invention;

FIG. 9 illustrates an exemplary transducer configured as a two-dimensional array for ultrasound treatment in accordance with an exemplary embodiment of the present invention;

FIGS. 10A-10F illustrate cross-sectional diagrams of exemplary transducers in accordance with other exemplary embodiments of the present invention;

FIG. 11 illustrates a schematic diagram of an acoustic coupling and cooling system in accordance with an exemplary embodiment of the present invention;

FIG. 12 illustrates a block diagram of an ultrasound treatment system combined with additional subsystems and methods of treatment monitoring and/or treatment imaging as well as a secondary treatment subsystem in accordance with an exemplary embodiment of the present invention; and

FIG. 13 illustrates a schematic diagram with imaging, therapy, or monitoring being provided with one or more active or passive oral inserts in accordance with an exemplary embodiment of the present invention.

DETAILED DESCRIPTION

The present invention may be described herein in terms of various functional components and processing steps. It should be appreciated that such components and steps may be realized by any number of hardware components configured to perform the specified functions. For example, the present invention may employ various medical treatment devices, visual imaging and display devices, input terminals and the like, which may carry out a variety of functions under the control of one or more control systems or other control devices. In addition, the present invention may be practiced in

any number of medical contexts and that the exemplary embodiments relating to a method and system for treating acne and sebaceous glands as described herein are merely indicative of exemplary applications for the invention. For example, the principles, features and methods discussed may be applied to any medical application. Further, various aspects of the present invention may be suitably applied to other applications.

In patients with acne it is desirable to temporarily or permanently destroy sebaceous glands. The depth at which these glands occur is approximately 1-7 mm, depending on skin thickness and body site. In accordance with various aspects of the present invention, a method and system for treating acne and sebaceous glands are provided. For example, in accordance with an exemplary embodiment, with reference to FIG. 1, an exemplary treatment system 100 configured to treat a region of interest (ROI) 106 comprises a control system 102, an imaging/therapy probe with acoustic coupling 104, and display system 108.

Control system 102 and display 108 can comprise various configurations for controlling functionality of probe 104 and system 100, including for example a microprocessor with software and a plurality of input/output and communication devices, a system for controlling electronic and/or mechanical scanning and/or multiplexing of transducers, a system for power delivery, systems for monitoring, systems for sensing the spatial position of the probe and/or temporal parameters of the transducers, and/or systems for handling user input and recording treatment input and results, among others. Imaging/therapy probe 104 can comprise various probe and/or transducer configurations. For example, probe 104 can be configured for a combined dual-mode imaging/therapy transducer, coupled or co-housed imaging/therapy transducers, a separate therapy probe and separate imaging probe, or a single therapy probe. In accordance with exemplary embodiments, imaging transducers may operate at frequencies from approximately 2 to 75 MHz or more, while therapy energy can be delivered at frequencies from approximately 2 to 50 MHz, with 2 MHz to 25 MHz being typical.

With reference to FIG. 2A, an exemplary treatment method and system are configured for initially imaging a region 222 within a region of interest 206 and displaying that region 224 on a display 208 to facilitate localization of the treatment area and surrounding structures, e.g., identification of sebaceous glands 232. After localization, delivery of ultrasound energy 220 at a depth, distribution, timing, and energy level to achieve the desired therapeutic effect of thermal ablation to treat a sebaceous gland 232 is provided. Before, during, and/or after therapy, i.e., before, during and/or after delivery of ultrasound energy, monitoring of the treatment area and surrounding structures can be conducted to further planning and assessing of the results and/or providing feedback to control system 202 and a system operator.

In accordance with an exemplary embodiment, localization can be facilitated through ultrasound imaging that can be used to define the position of a sebaceous gland and/or the depth of sebaceous glands over a region of interest. Such glands can be seen lying along hair follicles and their image may be further enhanced via signal and image processing. Ultrasound imaging can also be used for safety purposes, namely, to avoid injuring vital structures. In accordance with other exemplary embodiments, localization can also be accomplished without imaging region 222, but instead can be based on prior known depths of sebaceous glands or other target regions.

For ultrasound energy delivery, probe 204 and/or imaging/therapy transducers can be mechanically and/or electroni-

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cally scanned, for example along direction **226**, to place treatment zones over an extended area. A treatment depth **220** can be adjusted between a range of approximately 1 to 7 mm, and/or the greatest depth of sebaceous glands **232**. Such delivery of energy can occur through a repeated “image and burn” technique, i.e., imaging of the targeted sebaceous gland and then applying ultrasound energy, or through a “carpet bomb” technique, i.e., applying ultrasound energy at known depths over an extended area without initial or ongoing imaging.

With reference to FIG. **2B**, a treated zone **242** may extend over a line, plane, or surface, or over an extended zone across the sebaceous gland depth **240** that typically ranges from approximately 1 to 7 mm. Probe **204** can be mechanically and/or electronically scanned, for example directionally along **226**, to extend treatment zone **242** over a large area. Probe **204** can be further scanned or moved along a longer directional line **228** to further enlarge treatment zone **242**. For any treated zone **242**, as treated zone **242** increases in depth within region of interest **206**, the cross sectional area of treated zone **242** may increase in size from small to medium to large, i.e., at greater depths, the size of the treated lesion will increase. Furthermore a treated zone **242** can have a lesion shape expanding in cross section with depth, and/or be composed of the fusion of several smaller treatment zones. For example, a “cross-stitched” series of lesions, a wedge shaped series of lesions, or any suitably formed conformal lesions can be crated along treated zone **242**.

The ultrasound beam from probe **204** can be spatially and/or temporally controlled by changing the spatial parameters of the transducer, such as the placement, distance, treatment depth and transducer structure, as well as by changing the temporal parameters of transducer, such as the frequency, drive amplitude, and timing, with such control handled via control system **202**. Such spatial and temporal parameters can also be suitably monitored and/or utilized in open-loop and/or closed-loop feedback systems within treatment system **200**. As a result of such spatial and/or temporal control, conformal lesions of various, specifically targeted, shapes, sizes and orientations can be configured along treatment zone **242**.

In accordance with an exemplary embodiment, with reference to FIG. **2C**, one or more treated zones **242** can be configured to produce regions of heating and damage within the treatment layer in spatially defined patterns, such as a discrete locus of spaced treatment spots or two- or three- dimensional matrix of damage or destroyed tissue, e.g., a matrix of cross-stitched, ellipsoidal/cigar-shaped, wedge-shaped, mushroom-shaped or any other conformal lesions, rather than heating and destroying the entire volume of the target layer of tissue. In such a treatment where surrounding regions are spared of damage, the surrounding undamaged tissue aids rapid healing and recovery.

In accordance with another exemplary embodiment of the present invention, with reference to FIG. **2D**, an exemplary monitoring method may comprise monitoring the temperature profile or other tissue parameters of the region of interest **206**, such as attenuation, speed of sound, or mechanical properties such as stiffness and strain of the treatment region and suitably adjust the spatial and/or temporal characteristics and energy levels of the ultrasound therapy transducer of probe **204**. The results of such monitoring techniques may be indicated on display **208** by means of one-, two-, or three-dimensional images of monitoring results **250**, or may simply comprise a success or fail-type indicator **252**, or combinations thereof. Additional treatment monitoring techniques may be

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based on one or more of temperature, video, profilometry, and/or stiffness or strain gauges or any other suitable sensing technique.

In accordance with another exemplary embodiment, with reference to FIG. **2E**, a treatment system **200** can be configured for treatment over an expanded treatment region of interest **252** that includes a combination of tissues, such as subcutaneous fat/adipose tissue **216** and muscle **218**, among others. A multiple of such tissues may be treated including sebaceous glands in combination with at least one of epidermis **212**, dermis **214**, adipose tissue **216**, muscular fascia lying atop muscle tissue **218**, mucous membrane, hair bulb **230**, hair shaft **234**, hair follicle between hair bulb **230** and epidermis **212**, blood vessels, apocrine sweat glands, eccrine glands lying within dermis **214**, fat **216** or muscle **218**, and/or any other tissue of interest. For example, a treatment to region **220** of sebaceous gland **232** may be performed in combination with treatment to a region **260** of hair by suitable adjustment of the treatment spatial and/or temporal parameters of the transducers in probe **204**.

An exemplary control system **202** and display system **208** may be configured in various manners for controlling probe and system functionality for providing the various exemplary treatment methods illustrated above. For example, with reference to FIGS. **3A** and **3B**, in accordance with exemplary embodiments, an exemplary control system **300** can be configured for coordination and control of the entire therapeutic treatment process to achieve the desired therapeutic effect of thermal ablation to treat a sebaceous gland. For example, control system **300** can suitably comprise power source components **302**, sensing and monitoring components **304**, cooling and coupling controls **306**, and/or processing and control logic components **308**. Control system **300** can be configured and optimized in a variety of ways with more or less subsystems and components to implement the therapeutic system for controlled thermal injury of sebaceous glands, and the embodiments in FIGS. **3A** and **3B** are merely for illustration purposes.

For example, for power sourcing components **302**, control system **300** can comprise one or more direct current (DC) power supplies **303** configured to provide electrical energy for entire control system **300**, including power required by a transducer electronic amplifier/driver **312**. A DC current sense device **305** can also be provided to confirm the level of power going into amplifiers/drivers **312** for safety and monitoring purposes.

Amplifiers/drivers **312** can comprise multi-channel or single channel power amplifiers and/or drivers. In accordance with an exemplary embodiment for transducer array configurations, amplifiers/drivers **312** can also be configured with a beamformer to facilitate array focusing. An exemplary beamformer can be electrically excited by an oscillator/digitally controlled waveform synthesizer **310** with related switching logic.

The power sourcing components can also include various filtering configurations **314**. For example, switchable harmonic filters and/or matching may be used at the output of amplifier/driver **312** to increase the drive efficiency and effectiveness. Power detection components **316** may also be included to confirm appropriate operation and calibration. For example, electric power and other energy detection components **316** may be used to monitor the amount of power going to an exemplary probe system.

Various sensing and monitoring components **304** may also be suitably implemented within control system **300**. For example, in accordance with an exemplary embodiment, monitoring, sensing and interface control components **324**

may be configured to operate with various motion detection systems implemented within transducer probe **204** to receive and process information such as acoustic or other spatial and temporal information from a region of interest. Sensing and monitoring components can also include various controls, interfacing and switches **309** and/or power detectors **316**. Such sensing and monitoring components **304** can facilitate open-loop and/or closed-loop feedback systems within treatment system **200**.

Cooling/coupling control systems **306** may be provided to remove waste heat from an exemplary probe **204**, provide a controlled temperature at the superficial tissue interface and deeper into tissue, and/or provide acoustic coupling from transducer probe **204** to region-of-interest **206**. Such cooling/coupling control systems **306** can also be configured to operate in both open-loop and/or closed-loop feedback arrangements with various coupling and feedback components.

Processing and control logic components **308** can comprise various system processors and digital control logic **307**, such as one or more of microcontrollers, microprocessors, field-programmable gate arrays (FPGAs), computer boards, and associated components, including firmware and control software **326**, which interfaces to user controls and interfacing circuits as well as input/output circuits and systems for communications, displays, interfacing, storage, documentation, and other useful functions. System software and firmware **326** controls all initialization, timing, level setting, monitoring, safety monitoring, and all other system functions required to accomplish user-defined treatment objectives. Further, various control switches **308** can also be suitably configured to control operation.

An exemplary transducer probe **204** can also be configured in various manners and comprise a number of reusable and/or disposable components and parts in various embodiments to facilitate its operation. For example, transducer probe **204** can be configured within any type of transducer probe housing or arrangement for facilitating the coupling of transducer to a tissue interface, with such housing comprising various shapes, contours and configurations. Transducer probe **204** can comprise any type of matching, such as for example, electric matching, which may be electrically switchable; multiplexer circuits and/or aperture/element selection circuits; and/or probe identification devices, to certify probe handle, electric matching, transducer usage history and calibration, such as one or more serial EEPROM (memories). Transducer probe **204** may also comprise cables and connectors; motion mechanisms, motion sensors and encoders; thermal monitoring sensors; and/or user control and status related switches, and indicators such as LEDs. For example, a motion mechanism in probe **204** may be used to controllably create multiple lesions, or sensing of probe motion itself may be used to controllably create multiple lesions and/or stop creation of lesions, e.g. for safety reasons if probe **204** is suddenly jerked or is dropped. In addition, an external motion encoder arm may be used to hold the probe during use, whereby the spatial position and attitude of probe **104** is sent to the control system to help controllably create lesions. Furthermore, other sensing functionality such as profilometers or other imaging modalities may be integrated into the probe in accordance with various exemplary embodiments.

With reference to FIGS. **4A** and **4B**, in accordance with an exemplary embodiment, a transducer probe **400** can comprise a control interface **402**, a transducer **404**, coupling components **406**, and monitoring/sensing components **408**, and/or motion mechanism **410**. However, transducer probe **400** can be configured and optimized in a variety of ways with more or less parts and components to provide treatment of acne and

sebaceous, and the embodiments in FIGS. **4A** and **4B** are merely for illustration purposes.

Control interface **402** is configured for interfacing with control system **300** to facilitate control of transducer probe **400**. Control interface components **402** can comprise multiplexer/aperture select **424**, switchable electric matching networks **426**, serial EEPROMs and/or other processing components and matching and probe usage information **430** and interface connectors **432**.

Coupling components **406** can comprise various devices to facilitate coupling of transducer probe **400** to a region of interest. For example, coupling components **406** can comprise cooling and acoustic coupling system **420** configured for acoustic coupling of ultrasound energy and signals. Acoustic cooling/coupling system **420** with possible connections such as manifolds may be utilized to couple sound into the region-of-interest, control temperature at the interface and deeper into tissue, provide liquid-filled lens focusing, and/or to remove transducer waste heat. Coupling system **420** may facilitate such coupling through use of various coupling mediums, including air and other gases, water and other fluids, gels, solids, and/or any combination thereof, or any other medium that allows for signals to be transmitted between transducer active elements **412** and a region of interest. In addition to providing a coupling function, in accordance with an exemplary embodiment, coupling system **420** can also be configured for providing temperature control during the treatment application. For example, coupling system **420** can be configured for controlled cooling of an interface surface or region between transducer probe **400** and a region of interest and beyond by suitably controlling the temperature of the coupling medium. The suitable temperature for such coupling medium can be achieved in various manners, and utilize various feedback systems, such as thermocouples, thermistors or any other device or system configured for temperature measurement of a coupling medium. Such controlled cooling can be configured to further facilitate spatial and/or thermal energy control of transducer probe **400**.

In accordance with an exemplary embodiment, with additional reference to FIG. **11**, acoustic coupling and cooling **1140** can be provided to acoustically couple energy and imaging signals from transducer probe **1104** to and from the region of interest **1102**, to provide thermal control at the probe to region-of-interest interface **1110** and deeper into tissue, and to remove potential waste heat from the transducer probe at region **1144**. Temperature monitoring can be provided at the coupling interface via a thermal sensor **1146** to provide a mechanism of temperature measurement **1148** and control via control system **1106** and a thermal control system **1142**. Thermal control may consist of passive cooling such as via heat sinks or natural conduction and convection or via active cooling such as with peltier thermoelectric coolers, refrigerants, or fluid-based systems comprised of pump, fluid reservoir, bubble detection, flow sensor, flow channels/tubing **1144** and thermal control **1142**.

With continued reference to FIG. **4**, monitoring and sensing components **408** can comprise various motion and/or position sensors **416**, temperature monitoring sensors **418**, user control and feedback switches **414** and other like components for facilitating control by control system **300**, e.g., to facilitate spatial and/or temporal control through open-loop and closed-loop feedback arrangements that monitor various spatial and temporal characteristics.

Motion mechanism **410** can comprise manual operation, mechanical arrangements, or some combination thereof. For example, a motion mechanism **422** can be suitably controlled by control system **300**, such as through the use of accelerom-

eters, encoders or other position/orientation devices **416** to determine and enable movement and positions of transducer probe **400**. Linear, rotational or variable movement can be facilitated, e.g., those depending on the treatment application and tissue contour surface.

Transducer **404** can comprise one or more transducers configured for treating of acne and sebaceous glands and targeted regions. Transducer **404** can also comprise one or more transduction elements and/or lenses **412**. The transduction elements can comprise a piezoelectrically active material, such as lead zirconate titanate (PZT), or any other piezoelectrically active material, such as a piezoelectric ceramic, crystal, plastic, and/or composite materials, as well as lithium niobate, lead titanate, barium titanate, and/or lead metaniobate. In addition to, or instead of, a piezoelectrically active material, transducer **404** can comprise any other materials configured for generating radiation and/or acoustical energy. Transducer **404** can also comprise one or more matching layers configured along with the transduction element such as coupled to the piezoelectrically active material. Acoustic matching layers and/or damping may be employed as necessary to achieve the desired electroacoustic response.

In accordance with an exemplary embodiment, the thickness of the transduction element of transducer **404** can be configured to be uniform. That is, a transduction element **412** can be configured to have a thickness that is substantially the same throughout. In accordance with another exemplary embodiment, the thickness of a transduction element **412** can also be configured to be variable. For example, transduction element(s) **412** of transducer **404** can be configured to have a first thickness selected to provide a center operating frequency of approximately 2 kHz to 75 MHz, such as for imaging applications. Transduction element **412** can also be configured with a second thickness selected to provide a center operating frequency of approximately 2 to 50 MHz, and typically between 2 MHz and 25 MHz for therapy application. Transducer **404** can be configured as a single broadband transducer excited with at least two or more frequencies to provide an adequate output for generating a desired response. Transducer **404** can also be configured as two or more individual transducers, wherein each transducer comprises one or more transduction element. The thickness of the transduction elements can be configured to provide center-operating frequencies in a desired treatment range.

Transducer **404** may be composed of one or more individual transducers in any combination of focused, planar, or unfocused single-element, multi-element, or array transducers, including 1-D, 2-D, and annular arrays; linear, curvilinear, sector, or spherical arrays; spherically, cylindrically, and/or electronically focused, defocused, and/or lensed sources. For example, with reference to an exemplary embodiment depicted in FIG. **5**, transducer **500** can be configured as an acoustic array **502** to facilitate phase focusing. That is, transducer **500** can be configured as an array of electronic apertures that may be operated by a variety of phases via variable electronic time delays. By the term “operated,” the electronic apertures of transducer **500** may be manipulated, driven, used, and/or configured to produce and/or deliver an energy beam corresponding to the phase variation caused by the electronic time delay. For example, these phase variations can be used to deliver defocused beams **508**, planar beams **504**, and/or focused beams **506**, each of which may be used in combination to achieve different physiological effects in a region of interest **510**. Transducer **500** may additionally comprise any software and/or other hardware for generating, producing and or driving a phased aperture array with one or more electronic time delays.

Transducer **500** can also be configured to provide focused treatment to one or more regions of interest using various frequencies. In order to provide focused treatment, transducer **500** can be configured with one or more variable depth devices to facilitate treatment. For example, transducer **500** may be configured with variable depth devices disclosed in U.S. patent application Ser. No. 10/944,500, entitled “System and Method for Variable Depth Ultrasound”, filed on Sep. 16, 2004, having at least one common inventor and a common Assignee as the present application, and incorporated herein by reference. In addition, transducer **500** can also be configured to treat one or more additional ROI **510** through the enabling of sub-harmonics or pulse-echo imaging, as disclosed in U.S. patent application Ser. No. 10/944,499, entitled “Method and System for Ultrasound Treatment with a Multi-directional Transducer”, filed on Sep. 16, 2004, having at least one common inventor and a common Assignee as the present application, and also incorporated herein by reference.

Moreover, any variety of mechanical lenses or variable focus lenses, e.g. liquid-filled lenses, may also be used to focus and or defocus the sound field. For example, with reference to exemplary embodiments depicted in FIGS. **6A** and **6B**, transducer **600** may also be configured with an electronic focusing array **604** in combination with one or more transduction elements **606** to facilitate increased flexibility in treating ROI **610**. Array **604** may be configured in a manner similar to transducer **502**. That is, array **604** can be configured as an array of electronic apertures that may be operated by a variety of phases via variable electronic time delays, for example, $T_1, T_2 \dots T_j$. By the term “operated,” the electronic apertures of array **604** may be manipulated, driven, used, and/or configured to produce and/or deliver energy in a manner corresponding to the phase variation caused by the electronic time delay. For example, these phase variations can be used to deliver defocused beams, planar beams, and/or focused beams, each of which may be used in combination to achieve different physiological effects in ROI **610**.

Transduction elements **606** may be configured to be concave, convex, and/or planar. For example, in an exemplary embodiment depicted in FIG. **6A**, transduction elements **606A** are configured to be concave in order to provide focused energy for treatment of ROI **610**. Additional embodiments are disclosed in U.S. patent application Ser. No. 10/944,500, entitled “Variable Depth Transducer System and Method”, and again incorporated herein by reference.

In another exemplary embodiment, depicted in FIG. **6B**, transduction elements **606[B]** can be configured to be substantially flat in order to provide substantially uniform energy to ROI **610**. While FIGS. **6A** and **6B** depict exemplary embodiments with transduction elements **604** configured as concave and substantially flat, respectively, transduction elements **604** can be configured to be concave, convex, and/or substantially flat. In addition, transduction elements **604** can be configured to be any combination of concave, convex, and/or substantially flat structures. For example, a first transduction element can be configured to be concave, while a second transduction element can be configured to be substantially flat.

In accordance with another exemplary embodiment, transducer **404** may be suitably diced in two-dimensions to form a two-dimensional array. For example, with reference to FIG. **9**, an exemplary two-dimensional array **900** can be suitably diced into a plurality of two-dimensional portions **902**. Two-dimensional portions **902** can be suitably configured to focus on the treatment region at a certain depth, and thus provide respective slices **904, 907** of the treatment region. As a result,

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the two-dimensional array **900** can provide a two-dimensional slicing of the image plane of a treatment region, thus providing two-dimensional treatment.

With reference to FIGS. **8A** and **8B**, transducer **404** can be configured as single-element arrays, wherein a single-element **802**, e.g., a transduction element of various structures and materials, can be configured with a plurality of masks **804**, such masks comprising ceramic, metal or any other material or structure for masking or altering energy distribution from element **802**, creating an array of energy distributions **808**. Masks **804** can be coupled directly to element **802** or separated by a standoff **806**, such as any suitably solid or liquid material.

An exemplary transducer **404** can also be configured as an annular array to provide planar, focused and/or defocused acoustical energy. For example, with reference to FIGS. **10A** and **10B**, in accordance with an exemplary embodiment, an annular array **1000** can comprise a plurality of rings **1012**, **1014**, **1016** to **N**. Rings **1012**, **1014**, **1016** to **N** can be mechanically and electrically isolated into a set of individual elements, and can create planar, focused, or defocused waves. For example, such waves can be centered on-axis, such as by methods of adjusting corresponding transmit and/or receive delays, $T_1, T_2, T_3 \dots T_N$. An electronic focus can be suitably moved along various depth positions, and can enable variable strength or beam tightness, while an electronic defocus can have varying amounts of defocusing. In accordance with an exemplary embodiment, a lens and/or convex or concave shaped annular array **1000** can also be provided to aid focusing or defocusing such that any time differential delays can be reduced. Movement of annular array **800** in one, two or three-dimensions, or along any path, such as through use of probes and/or any conventional robotic arm mechanisms, may be implemented to scan and/or treat a volume or any corresponding space within a region of interest.

Transducer **404** can also be configured in other annular or non-array configurations for imaging/therapy functions. For example, with reference to FIGS. **10C-10F**, a transducer can comprise an imaging element **1012** configured with therapy element(s) **1014**. Elements **1012** and **1014** can comprise a single-transduction element, e.g., a combined imaging/transducer element, or separate elements, can be electrically isolated **1022** within the same transduction element or between separate imaging and therapy elements, and/or can comprise standoff **1024** or other matching layers, or any combination thereof. For example, with particular reference to FIG. **10F**, a transducer can comprise an imaging element **1012** having a surface **1028** configured for focusing, defocusing or planar energy distribution, with therapy elements **1014** including a stepped-configuration lens configured for focusing, defocusing, or planar energy distribution.

In accordance with various exemplary embodiments of the present invention, transducer **404** may be configured to provide one, two and/or three-dimensional treatment applications for focusing acoustic energy to one or more regions of interest. For example, as discussed above, transducer **404** can be suitably diced to form a one-dimensional array, e.g., transducer **602** comprising a single array of sub-transduction elements.

In accordance with another exemplary embodiment, transducer **404** may be suitably diced in two-dimensions to form a two-dimensional array. For example, with reference to FIG. **9**, an exemplary two-dimensional array **900** can be suitably diced into a plurality of two-dimensional portions **902**. Two-dimensional portions **902** can be suitably configured to focus on the treatment region at a certain depth, and thus provide respective slices **904**, **907** of the treatment region. As a result,

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the two-dimensional array **900** can provide a two-dimensional slicing of the image plane of a treatment region, thus providing two-dimensional treatment.

In accordance with another exemplary embodiment, transducer **404** may be suitably configured to provide three-dimensional treatment. For example, to provide three-dimensional treatment of a region of interest, with reference again to FIG. **1**, a three-dimensional system can comprise a transducer within probe **104** configured with an adaptive algorithm, such as, for example, one utilizing three-dimensional graphic software, contained in a control system, such as control system **102**. The adaptive algorithm is suitably configured to receive two-dimensional imaging, temperature and/or treatment or other tissue parameter information relating to the region of interest, process the received information, and then provide corresponding three-dimensional imaging, temperature and/or treatment information.

In accordance with an exemplary embodiment, with reference again to FIG. **9**, an exemplary three-dimensional system can comprise a two-dimensional array **900** configured with an adaptive algorithm to suitably receive **904** slices from different image planes of the treatment region, process the received information, and then provide volumetric information **906**, e.g., three-dimensional imaging, temperature and/or treatment information. Moreover, after processing the received information with the adaptive algorithm, the two-dimensional array **900** may suitably provide therapeutic heating to the volumetric region **906** as desired.

In accordance with other exemplary embodiments, rather than utilizing an adaptive algorithm, such as three-dimensional software, to provide three-dimensional imaging and/or temperature information, an exemplary three-dimensional system can comprise a single transducer **404** configured within a probe arrangement to operate from various rotational and/or translational positions relative to a target region.

To further illustrate the various structures for transducer **404**, with reference to FIG. **7**, ultrasound therapy transducer **700** can be configured for a single focus, an array of foci, a locus of foci, a line focus, and/or diffraction patterns. Transducer **700** can also comprise single elements, multiple elements, annular arrays, one-, two-, or three-dimensional arrays, broadband transducers, and/or combinations thereof, with or without lenses, acoustic components, and mechanical and/or electronic focusing. Transducers configured as spherically focused single elements **702**, annular arrays **704**, annular arrays with damped regions **706**, line focused single elements **708**, 1-D linear arrays **710**, 1-D curvilinear arrays in concave or convex form, with or without elevation focusing, 2-D arrays, and 3-D spatial arrangements of transducers may be used to perform therapy and/or imaging and acoustic monitoring functions. For any transducer configuration, focusing and/or defocusing may be in one plane or two planes via mechanical focus **720**, convex lens **722**, concave lens **724**, compound or multiple lenses **726**, planar form **728**, or stepped form, such as illustrated in FIG. **10F**. Any transducer or combination of transducers may be utilized for treatment. For example, an annular transducer may be used with an outer portion dedicated to therapy and the inner disk dedicated to broadband imaging wherein such imaging transducer and therapy transducer have different acoustic lenses and design, such as illustrated in FIG. **10C-10F**.

Moreover, such transduction elements **700** may comprise a piezoelectrically active material, such as lead zirconate titanate (PZT), or any other piezoelectrically active material, such as a piezoelectric ceramic, crystal, plastic, and/or composite materials, as well as lithium niobate, lead titanate, barium titanate, and/or lead metaniobate. Transduction ele-

ments **700** may also comprise one or more matching layers configured along with the piezoelectrically active material. In addition to or instead of piezoelectrically active material, transduction elements **700** can comprise any other materials configured for generating radiation and/or acoustical energy. A means of transferring energy to and from the transducer to the region of interest is provided.

In accordance with another exemplary embodiment, with reference to FIG. **12**, an exemplary treatment system **200** can be configured with and/or combined with various auxiliary systems to provide additional functions. For example, an exemplary treatment system **1200** for treatment of acne and sebaceous glands can further comprise an auxiliary imaging modality **1272** and/or auxiliary monitoring modality **1274** may be based upon at least one of photography and other visual optical methods, magnetic resonance imaging (MRI), computed tomography (CT), optical coherence tomography (OCT), electromagnetic, microwave, or radio frequency (RF) methods, positron emission tomography (PET), infrared, ultrasound, acoustic, or any other suitable method of visualization, localization, or monitoring of the region-of-interest, including imaging/monitoring enhancements. Such imaging/monitoring enhancement for ultrasound imaging via probe **1204** and control system **1202** can comprise M-mode, persistence, filtering, color, Doppler, and harmonic imaging among others; furthermore an ultrasound treatment system **1270**, as a primary source of treatment, may be combined with a secondary source of treatment **1276**, including radio frequency (RF), intense pulsed light (IPL), laser, infrared laser, microwave, or any other suitable energy source.

In accordance with another exemplary embodiment, with reference to FIG. **13**, treatment composed of imaging, monitoring, and/or therapy to a region of interest **1302** and/or **1308** may be aided, augmented, and/or delivered with passive or active devices **1304** and/or **1306** within the oral and/or nasal cavity, respectively. For example, if passive or active device **1304** and/or **1306** are second transducers or acoustic reflectors acoustically coupled to the mucous membranes it is possible to obtain through transmission, tomographic, or round-trip acoustic waves which are useful for treatment monitoring, such as in measuring acoustic speed of sound and attenuation, which are temperature dependent; furthermore such transducers could be used to treat and/or image. In addition an active, passive, or active/passive object **1304** and/or **1306** may be used to flatten the skin, and/or may be used as an imaging grid, marker, or beacon, to aid determination of position. A passive or active device **1304** and/or **1306** may also be used to aid cooling or temperature control. Natural air in the oral cavity and/or nasal cavity may also be used as passive device **1304** and/or **1306** whereby it may be utilized to as an acoustic reflector to aid thickness measurement and monitoring function.

The present invention may be described herein in terms of various functional components and processing steps. It should be appreciated that such components and steps may be realized by any number of hardware components configured to perform the specified functions. For example, the present invention may employ various medical treatment devices, visual imaging and display devices, input terminals and the like, which may carry out a variety of functions under the control of one or more control systems or other control devices. In addition, the present invention may be practiced in any number of medical contexts and that the exemplary embodiments relating to a system as described herein are merely indicative of exemplary applications for the invention. For example, the principles, features and methods discussed may be applied to any medical application. Further, various

aspects of the present invention may be suitably applied to other applications, such as other medical or industrial applications.

What is claimed is:

1. A method for providing treatment of acne and sebaceous glands, said method comprising:

localizing at least one targeted region within a region of interest, said localizing configured for identifying at least one sebaceous gland;

targeting delivery of ablative ultrasound energy from a transducer probe to said at least one sebaceous gland at a depth of about 1 to about 7 mm; and

monitoring results of said targeted delivery within said at least one sebaceous gland during and after said targeted delivery to continue planning of treatment.

2. The method of claim **1**, wherein said localizing at least one targeted region comprises imaging a region of interest to identify said at least one sebaceous gland.

3. The method of claim **1**, said targeting of delivery of ablative ultrasound energy comprises destroying the function of said sebaceous gland within a specified treatment depth identified through localization of said sebaceous gland.

4. The method of claim **1**, wherein said targeting of delivery of ablative ultrasound comprises adjustable control of spatial parameters and temporal parameters of said transducer probe to generate conformal lesions of specifically targeted shapes, sizes and orientations.

5. The method of claim **1**, wherein said targeting delivery of ablative ultrasound comprises producing said treatment regions in spatially defined patterns to facilitate healing of tissue.

6. The method according to claim **5**, wherein said producing said treatment regions in spatially defined patterns comprises producing a discrete locus of spaced lesions comprising at least one of cross-stitch, cigar-shaped, or wedge-shaped lesions.

7. The method of claim **1**, wherein said monitoring results comprises measurement of results of treatment of said at least one sebaceous gland as visualized during and after said target delivery of ablative ultrasound.

8. The method of claim **1**, wherein said monitoring results comprises monitoring the temperature profile of said targeted region.

9. The method of claim **1**, wherein said targeted of delivery of ablative ultrasound comprises producing of a matrix of spaced treatment spots comprising at least one of two-dimensional and three-dimensional matrix of lesions along a scanned pattern created by scanning of said transducer probe.

10. The method according to claim **5**, wherein said producing said treatment regions in spatially defined patterns comprises producing a discrete locus of spaced conformal lesions based on control of spatial and temporal parameters.

11. The method according to claim **1**, wherein said localizing at least one targeted region comprises generating three-dimensional imaging information and said targeting comprises treating three-dimensional treatment region.

12. The method according to claim **1**, wherein said targeting of delivery further comprises cooling through any tissue regions between and including skin and said at least one sebaceous gland to facilitate treatment.

13. A method for providing treatment of acne and sebaceous glands, said method comprising:

localizing at least one targeted region for identifying at least one sebaceous gland;

targeting delivery of ablative ultrasound energy from a transducer probe to said at least one sebaceous gland at a specified treatment depth of about 1 to about 7 mm for

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destroying any function of said at least one sebaceous gland within said specified treatment depth, wherein said targeting of delivery comprises delivery of ablative ultrasound energy in spatially defined patterns producing a discrete locus of spaced lesions comprising at least one of a cross-stitch, a cigar-shaped, and a wedge-shaped lesion; and

monitoring results of said targeted delivery within said at least one sebaceous gland during and after said targeted delivery to continue planning of treatment.

14. The method of claim **13**, further comprising producing spatially defined patterns in said at least one targeted region to facilitate healing of tissue.

15. The method according to claim **14**, wherein said producing said spatially defined patterns in said at least one targeted region further comprises producing a discrete locus of spaced conformal lesions based on control of spatial and temporal parameters.

16. The method according to claim **13**, further comprising generating three-dimensional imaging information of said least one sebaceous gland.

17. The method according to claim **16**, further comprising treating a three-dimensional treatment region as defined by said three-dimensional imaging information of said least one sebaceous gland.

18. A method of providing a treatment for acne by a reduction in function of pilosebaceous glands, the method comprising:

- imaging a treatment area below a skin surface, said treatment area comprising at least portion of said pilosebaceous gland;
- identifying at least portion of said pilosebaceous gland in said treatment area;
- delivering ultrasound energy to said at least portion of said pilosebaceous gland;

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coagulating said least a portion of said pilosebaceous gland; and
 monitoring said pilosebaceous gland for a reduction in function; thereby reducing an appearance of acne on said skin surface.

19. The method of claim **18** further comprising producing spatially defined patterns in said treatment area to facilitate healing of tissue.

20. The method according to claim **19**, wherein said producing spatially defined patterns in said treatment area comprises producing a discrete locus of spaced conformal lesions based on control of spatial and temporal parameters.

21. The method according to claim **19**, wherein said producing spatially defined patterns in said treatment area comprises producing a discrete locus of spaced lesions comprising at least one of cross-stitch, cigar-shaped, or wedge-shaped lesions.

22. The method of claim **18**, wherein said delivering ultrasound energy to said at least portion of said pilosebaceous gland further comprises adjustably controlling of spatial parameters and temporal parameters of a transducer probe to generate conformal lesions of specifically targeted shapes, sizes and orientations.

23. The method of claim **18**, further comprising producing of a matrix of spaced treatment spots comprising at least one of two-dimensional and three-dimensional matrix of lesions.

24. The method according to claim **18**, further comprising generating three-dimensional imaging information comprising generating three-dimensional imaging information of said least one sebaceous gland.

25. The method according to claim **18** further comprising treating a three-dimensional treatment region as defined by said three-dimensional imaging information of said least one sebaceous gland.

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